VA Western New York Healthcare System
(VAWNYHS)
Buffalo, New York 14215

CHEMICAL HYGIENE PLAN
AND LABORATORY SAFETY MANUAL
FOR
RESEARCH LABORATORIES

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CHEMICAL HYGIENE PLAN AND LABORATORY SAFETY MANUAL FOR RESEARCH LABORATORIES (CHP)

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Alphabetical Listing of Abbreviations/Acronyms

ACGIH - American Conference of Government Industrial Hygienist

BBP - Blood Borne Pathogens

CDC - Centers for Disease Control and Prevention

CHP - Chemical Hygiene Plan

CRADO - Chief Research and Development Officer

EPA - Environmental Protection Agency

FMS - Facilities Management Service

HHCs - Highly Hazardous Chemicals

LSC - Laboratory Safety Committee

LSO - Laboratory Safety Officer

MSDS - Material Safety Data Sheet

MSDSs - Material Safety Data Sheets

NIH - National Institutes of Health

NRC - Nuclear Regulatory Commission

OBA - Office of Biotechnology Activities

OSHA - Occupational Safety and Health Administration

PEL - Permissible Exposure Limit

PI - Principal Investigator

PPE - Personal Protective Equipment

R&D - Research and Development

RCHP - Research Chemical Hygiene Plan

RCRA – Resource Conservation and Recovery Act

RSO - Radiation Safety Officer

SAA - satellite accumulation area

SDS – Safety Data Sheet

SDSs – Safety Data Sheets

SOPs - Standard Operating Procedures

SRS - Subcommittee on Research Safety

TLV - Threshold Limit Value

VMU - Veterinary Medical Unit

I. PURPOSE

The purpose of this *Chemical Hygiene Plan and Laboratory Safety Manual for Research Laboratories* (hereafter referred to simply as the "Chemical Hygiene Plan" or "**CHP**") is to provide a service-wide plan for the protection of all staff and visitors from hazards associated with chemicals and other hazardous materials utilized within the Research Service.

II. POLICY

The Research Service maintains a program to educate employees on a continuous basis and to protect them from health hazards associated with hazardous chemicals in the laboratory by keeping exposure to below permissible limits and ensuring compliance with pertinent Federal, State and local regulations. Protection is secured for patients, research personnel, visitors, property and the environment.

III. SCOPE

Under this Chemical Hygiene Plan, research laboratory personnel will be trained regarding the hazardous chemicals and materials, to which they may be exposed, by means of a hazard communication program, product labeling, Safety Data Sheets (SDSs) or Material Safety Data Sheets (**MSDS**s), training and monitoring compliance of the personnel by the Laboratory Safety Officer (**LSO**). Research laboratories are included in the medical center-wide written occupational safety and health program. The role and responsibilities of the research office is defined within this program. Research offices must also maintain a Research Safety Program that is consistent with VA policies, Federal statutes and regulations from Occupational Safety and Health Administration (**OSHA**), the Environmental Protection Agency (**EPA**), the Nuclear Regulatory Commission (**NRC**), etc., and any applicable state and local requirements. All applicable National Institutes of Health (**NIH**) and/or Centers for Disease Control and Prevention (**CDC**) guidelines must be followed.

A. DEFINITIONS

1. **Biohazards**

   Biohazards include, but are not limited to, the following:

   (a) Pathogens and/or etiologic agents, human and animal tissues including blood and body secretions, and human cell lines corresponding to BSL 1-4 ("*Biosafety in Microbiological and Biomedical Laboratories*," (most recent edition);

   (b) Toxins produced by microbial organisms (see Centers for Disease Control and Prevention (CDC)-National Institutes of Health (NIH). "*Biosafety in Microbiological and Biomedical Laboratories,"* (most recent edition)

   (c) Poisonous, toxic, parasitic and venomous animals or plants.

Recombinant DNA molecules (see "*NIH Guidelines for Research Involving DNA Molecules*," April 2002; also May 28, 2002, addendum: "Compliance with the NIH

Guidelines for Research Involving Recombinant DNA Molecules" http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-052.html).

(d) Select agents, as specified in Title 42 Code of Federal Regulations (see Title 42 CFR Part 72, *Interstate Shipment of Etiologic Agents*).

(e) Animals experimentally or naturally exposed to any of the above (see CDC-NIH. *Biosafety in Microbiological and Biomedical Laboratories*, (most recent edition).

2. **Chemical Hazards**
Chemical hazards include any substance or mixture of substances with properties capable of producing adverse effects on the health and/or safety of humans (see Title 29 CFR Part 1910.1450, *Occupational Exposure to Hazardous Chemicals in Laboratories*). Chemical hazard categories include, but are not limited to, the following:

(a) Corrosives

(b) Toxic substances (poisons, irritants, asphyxiates)

(c) Sensitizers

(d) Carcinogens, mutagens and/or teratogens

(e) Flammables

(f) Radioisotopes

An alphabetical list of hazardous chemicals per New York State guidelines may be found at: http://www.sec.ny.gov/reg/15588.html

3. **Physical Hazards**
Physical hazards include, but are not limited to the following:

(a) Ionizing and non-ionizing radiation (Handbook 1200.8, App. E)

(b) Noise

(c) Vibration

(d) Extremes of temperature and pressure

(e) Explosive hazards

(f) Electrical hazards, and

(g) Mechanical hazards.

IV. RESPONSIBILITES

A. Medical Center Director

The Medical Center Director is responsible for:

1. Ensuring that the safety program is staffed adequately and that resources are available to maintain full compliance with all applicable regulations and standards of safety.

2. Ensuring that all Research personnel are included in the facility Occupational Safety and Health program and that research space is included in annual workplace inspections. NOTE: Research personnel are covered by all other facility safety programs (*e.g.*, respiratory protection program, fire safety program, etc.)

3. In cooperation with the Associate Chief of Staff for Research and Development (**ACOS/R&D**), ensuring that measures for the security of the research laboratories and surrounding space is appropriate.

B. Associate Chief of Staff for Research and Development (ACOS/R&D)

The ACOS/R&D is responsible for:

1. Ensuring that safety related communications from the Chief Research and Development Officer (**CRADO**) are disseminated to appropriate personnel in a timely manner after receipt.

2. Overseeing all phases of the Chemical Hygiene Plan (CHP).

3. Ensures continuous development of procedures on the use, storage, spill control and disposal of hazardous chemicals utilized.

C. Research and Development (R&D) Committee

The R&D Committee is responsible for:

1. Reviewing all R&D proposals.

2. Establishing a Subcommittee on Research Safety (**SRS**) and Laboratory Safety Committee (**LSC**).

   (a) Ensuring the SRS review of those protocols and/or submissions for funding that involve safety hazards to personnel and/or the environment.

   (b) Ensuring the LSC review and educate research laboratory staff on all current regulations related to laboratory safety.

3. Acting upon SRS recommendations for approval or non-approval of reviewed proposals for submission to VA Central Office

4. Reviewing and acting upon SRS and LSC minutes.

5. Ensuring the development and implementation of the laboratory Chemical Hygiene Plan. Appointing a **Research Service Lab Safety Officer,** to provide technical guidance on the implementation of the Plan. The Research Lab Safety Officer should be a voting member of the SRS and Chair of the LSC.

D. Research Service Lab Safety Officer

The Research Service Lab Safety Officer is responsible for:

1. Providing technical guidance on the implementation of the Chemical Hygiene Plan.

2. Investigating incidents or unsafe conditions concerning hazardous chemicals and reporting to the R&D Committee any significant findings.

3. Assisting with inspections of the Research Service laboratories.

4. Recommending less hazardous chemicals to be substituted, where possible, for more hazardous chemicals to minimize hazardous waste.

5. Coordinating waste disposal with the Medical Center Safety Office.

E. Subcommittee on Research Safety

SRS is responsible for:

1. Reviewing all research activities involving biological, chemical, physical and radiation hazards for compliance with all applicable regulations, policies, and guidelines prior to initiation of the project. This includes a review of all research applications for funding that will be conducted at the VA facility or by VA personnel with VA funding located off-site.

   (a) All research projects involving biological, chemical, physical and radiation hazard must be approved by the SRS and then by the R&D Committee prior to commencement.

2. Annually reviewing all research protocols involving biological, chemical, physical and radiation hazards, regardless of funding status or source.

3. Ensuring that a complete list of all products containing chemicals designated or identified by OSHA and /or EPA as "hazardous" (see Title 29 CFR Part 1910.1200, *Hazardous Communications* or Title 40 CFR Part 261, *Identification and Listing of Hazardous Waste*, and/or applicable state requirements) has been submitted to the Laboratory Safety Officer for review.

F. Principal Investigator (PI) or Laboratory Director

The Principal Investigator (**PI**) is responsible for the implementation and oversight of this policy in his/her laboratory. This includes providing students and staff with specific information and practical laboratory training beyond this plan on the unique hazards of their lab work. The PI is responsible for the day-to-day health and safety management of their laboratories and ensuring compliance with facility waste disposal requirements.

The PI or Laboratory Director is responsible for research activities conducted in assigned space, including:

1 Submitting a completed Research Proposal Safety Survey (RPSS) (VA Form 10-0398) to the medical center research office along with each research proposal to be submitted for funding.

(a) The complete research proposal must accompany the survey.

(b) The research office arranges for review of the proposal and evaluation by SRS.

(c) Within (or attached to) the SRS safety protocol review form, a complete list of chemicals defined as "hazardous" to be used must be submitted. NOTE: Not submitting such a list will result in failure to obtain approval by the facility Safety Officer. Review and approval by the Safety Officer is required prior to local review of protocols by the R&D Committee.

2. Ensuring that active protocols and new pilot projects have been reviewed by SRS, regardless of funding status or source.

3. **If a Principal Investigator proposes work to involve recombinant DNA (rDNA) classifications other than those in Class III-F, prior approval must be obtained from:** (i) NIH Office of Biotechnology activities (**OBA**), (ii) the State University at Buffalo Biosafety Committee, (iii) VA SRS**. (Appendix A).**

4. Identifying laboratory specific hazards, and:

(a) Ensuring that all personnel receive training specific to the hazard(s).

(b) Advising laboratory personnel of any potential risk to themselves or the research environment.

(c) Establishing and enforcing standards of practice which minimize employee exposures to biological, chemical, physical, and radiation hazards.

5. Supervising the performance of the laboratory staff to ensure the correct use of required safety practices and techniques (including Personal Protective Equipment).

6. Ensuring that all accidents are reported to the Employee Health Office, the Research Office and the facility safety office using appropriate VHA forms.

7. Securing approval of the R&D Committee through the SRS for any significant changes made in the original research plan.

8. Coordinating with appropriate safety staff such as the Safety Office or the Radiation Safety Officer for removal or disposal of all chemicals, biological agents, radioactive materials and waste generated by these materials.

9. **When vacating an R & D lab, the PI shall leave the laboratory in compliance with all VA safety and OSHA hazardous waste and disposal requirements.**

The facility will take action against laboratories left in a condition requiring station assistance to meet these compliance standards.

10. Ensuring that a copy of the laboratory's Chemical Hygiene Plan is readily available to all employees in their work area, that employees have been trained in the contents of the Plan and that all provisions of the Plan are implemented in all laboratories under the PI's supervision.

11. Maintaining employee exposure to hazardous chemicals in laboratory activities at the lowest reasonable levels. At no time may employee exposures to chemicals exceed the Permissible Exposure Limits established by OSHA

12. Maintaining an up-to-date inventory of all hazardous chemicals located in the laboratory.

    (a) Ensuring that all laboratory personnel know the location of this inventory.

    (b) Providing this inventory to the facility Safety Officer.

    (c) Ensures that all laboratory hazardous chemicals are stored, labeled and disposed of in compliance with Federal, State and Local regulations.

13. Managing all biological and chemical waste in accordance with Federal, State, and Local regulations and all VA, VHA, and facility policies.

    (a) Seeking technical assistance when needed to ensure proper waste management.

    (b) Implementing waste reduction techniques, where appropriate.

14. Investigating and correcting deficiencies cited during all inspections of work areas. Submitting a written abatement plan for all deficiencies cited during inspections to SRS within the specified time limits.

G. Laboratory Staff

1. Plans and conducts each operation in accordance with procedures as outlined in the Chemical Hygiene Plan.

2. Reads, becomes familiar with, and complies with the CHP and other applicable policies in the Medical Center, Research Service Safety Manuals and the Radiation Protection Program Manual (when applicable).

3. Wear and utilize appropriate Personal Protective Equipment (**PPE**) as required for the operation being conducted. **Lab coats must be worn when working in the lab; such protective outer wear worn in the laboratory is not to be worn elsewhere outside the laboratory**. Designated garments will be provided for wear in the animal facility (Veterinary Medical Unit, VMU), and should not be worn outside that area after exposure to animals. **The wearing of open-toed shoes and sandals is prohibited in laboratories and the VMU**.

4. Adhere to appropriate work practices/engineering controls for the operation being conducted. All staff must review all new procedures with the laboratory

supervisor and be aware of potential hazards that might result when performing any procedure.

5. Never attempt to operate any equipment without prior instruction from someone who knows how to use it.

6. Promptly report unsafe conditions or unsafe use of hazardous chemicals or radioactive materials to their supervisor.

7. Staff are required to participate in workplace monitoring and/or medical surveillance as appropriate.

8. All staff must know where the fire extinguishers, eyewashes, emergency showers and exits are located in the building. Hallways must remain unobstructed. All staff must participate in annual safety training.

9. All laboratory personnel who use, store and handle hazardous chemicals or radioactive materials are required to abide by the policies set forth in this Chemical Hygiene Plan or the Radiation Protection Program Manual (when applicable).

10. Food, drink, cosmetics and medication for consumption or use are prohibited inside laboratories. Never dispose of food wrappers or containers in laboratory waste receptacles.

11. Certain procedures necessitate the wearing of gloves outside the lab, usually when accessing common lab areas. However, be certain NOT to wear gloves potentially contaminated with hazardous materials outside the lab.

12. **WASH HANDS OFTEN**, even if all work has been performed wearing gloves.

13. If working with human blood or blood products, see Section E and **Appendices I and J**.

14 Mouth pipetting of any kind is forbidden.

15. ALL injuries (needle sticks, cuts, abrasions) and accidents are to be **reported to the supervisor IMMEDIATELY**. Never assume an injury or exposure is insignificant. Report it to your supervisor, the Research office or ACOS/R&D, and have it evaluated by **Employee Health or the VA Emergency Room**. Accident, injury and/or illness forms (as applicable), will be initiated by Employee Health or Emergency Room staff.

16. **In the event the eyes are contaminated**, wash exhaustively at the eye wash station, report the incident to the supervisor immediately and have the affected personnel report to **Employee Health or the VA Emergency Room**.

17 .Minimize all chemical exposures. Skin contact with chemicals should be avoided. Dried, cracked and broken skin on hands and arms MUST be covered with gloves at all times.

18. Maintain adequate ventilation when working with dry ice or cryogenic solutions. Exposure to dry ice gases in an enclosed space for an extended period may be lethal.

19. Appropriate gloves and face shields are provided and must be used when working with liquid nitrogen. Wearing an additional pair of safety goggles under the face shield is recommended.

20. Be sure to keep flammables and combustibles from flames, Bunsen burners and hot plates.

21. Keep work area clean and uncluttered. Chemicals and equipment should be properly labeled and stored. Clean up the work space upon the completion of each task or at the end of the day.

H. Safety Office:

1. Reviews the CHP and program for implementation to ensure conformity with the requirements of OSHA and other regulatory agencies.

2. Provides guidance on standard operating procedures (**SOPs**) developed by Principal Investigators for the safe handling and use of substances with highly acute toxicity, select carcinogens, mutagens, and reproductive toxins).

3. Arranges for proper disposal of hazardous waste from Research.

4. Conducts / arranges for personal exposure monitoring (air sampling) when there is reason to believe that exposures may exceed the OSHA Action Level.

5. Conducts/coordinates hazardous waste disposal from satellite storage areas in research laboratories.

V. GENERAL LABORATORY PRACTICES

A. Each lab is required to keep a written chemical inventory. This is submitted to the Safety Office annually. Additionally, any chemical ordered for use the first time, should be included on the Research Safety form submitted with the new protocol.

B. **Each chemical in the lab will have a link to the MAXCOM/GHS internet based Hazardous Chemical Management Database for access to Material Safety Data Sheet (MSDS) or Safety Data Sheet (SDS).** Before work using a certain chemical begins, read the MSDS or SDS for hazards and precautions associated with use and disposal. Minimize all chemical exposures. General precautions for handling all laboratory chemicals should be adopted, rather than specific guidelines for particular chemicals.

C. **The following additional documents must be present in the laboratory:** Chemical Hygiene Plan, Chemical Inventory. Every person in the lab must be able to locate each of these documents.

D. Each common room has a Principal Investigator in charge of the room. That person is in charge of general operation, safety and security of that area. Common areas have their own set of safety issues:

1. Post a message on the outside of the door of a common area indicating any use of the room that is of potential hazard to others entering.

2. Keep the area neat and clean. Each investigator who uses the common area is responsible to ensure that his/her staff cleans the area of any waste or chemicals when they are finished.

3. Dispose of gels containing ethidium bromide as a chemical hazard (*i.e.*, collect for hazardous waste pick-up).

4. If you have used radioactive materials in a common (shared) room, follow all applicable contamination survey requirements as defined in the Radiation Protection Program Manual.

5. Do not store combustibles within 18" of the ceiling.

6. Do not store gallon containers above eye level.

7. **Signage to be affixed to exterior laboratory door:**

   (a) Radioactive materials (depending the amount of activity present in a room, signage may be required as determined by the Health Physics Office).

   (b) Biological hazard sign

   (c) Emergency contact phone numbers

8. Children and other unauthorized personnel are NOT permitted in the laboratory areas, without the prior approval of the lab supervisor. If a laboratory is a radioactive material use area, the Radiation Safety Committee must approve access to that area for individuals less than eighteen years of age.

For general safety procedures pertaining to the veterinary medical unit (VMU), see **APPENDIX K**. "General Safety Procedures for the Veterinary Medical Unit (VMU)

VI. SPECIAL LABORATORY PROCEDURES

A. Compressed Gases

1. Cylinders must be secured at all times to prevent accidents.

2. Containers must be clearly labeled with the name of the contents in accordance with Hazard Communication and OSHA regulations.

3. Hand trucks or dollies with a securing device installed must be used when moving cylinders.

4. Cylinders should be kept away from any source of ignition and should be closed at the main cylinder valve when not in use.

B. Flammable Gases

1. No more than two cylinders should be manifolded together. When more than one cylinder of a highly flammable gas is to be used in one room, special approval by the Medical Center Safety Office must be attained.

2. Standby cylinders (full or empty) should not be stored in the laboratory.

3. Valves on all flammable gas cylinders must be shut off when the unit is unattended.

C. Radioactive Material Procedures

1. Permission to use radioactive material and approval of any protocol using radioactive materials must be obtained through the Radiation Safety Committee before use of those materials. After these approvals are obtained, strict adherence to the guidelines set forth in the Medical Center's Radiation Protection Program Manual will be followed.

2. Each laboratory authorized to use radioactive materials will maintain a complete inventory of radioactive materials using the"Inventory/Disposal Record" form issued by the Health Physics Office when radioactive materials are received. All radioactive material usage, storage and disposal activities are audited periodically by Health Physics Staff using the "Radioactive Material Inspection Report - Research" form.

3. All radioactive waste will be placed in an appropriate waste receptacle and labeled "Radioactive Material." A record of disposal will be entered on the "Inventory/Disposal Record" form and on the waste receptacle form, "Radioactive Waste Storage Container Log". Radioactive Waste can only be disposed of through the Health Physics Office. Liquid and solid waste must be separated. If authorized, there are some materials that may be disposed of through the sewer in an authorized "Radioactive Materials Sink." Record of this disposal is to be entered on the above form and on the "Radioactive Waste Sink Disposal Log' form posted at each radioactive sink.

For specific procedures pertinent to use of radioactive materials in the Veterinary Medical Unit (VMU), see **APPENDIX L**. "Standard Operating Procedures for Radioactive Materials Safety in the Veterinary Medical Unit (VMU).

D. Acidic/Caustic Materials

1. If strong acids or alkalis are being used, a shield or barrier should be used to control spills.

2. Wear aprons, proper gloves and face shield when handling highly corrosive materials.

3. Do not mouth pipette or sniff reagents.

4. Use great care when diluting reagents. When diluting acids **slowly add acid to water** and mix slowly.

5. When transporting acids on a cart, place them in heavy plastic secondary containment carriers with at least twice the volume of the acid being transported.

6. Maintain adequate ventilation.

7. Special precautions should be taken for oxidizing agents (e.g., chromic acid, potassium dichromate, etc.). *Consult MSDSs or SDSs in MAXCOM database.*

E. Formaldehyde/Formalin

1. All operations/procedures using formaldehyde/formalin must be evaluated to determine the potential exposure to formaldehyde.

2. Employees at risk of potential over exposure to formaldehyde when using formalin will be monitored as specified by OSHA. The Safety Office will schedule monitoring as necessary to comply with OSHA requirements.

3. Compliance with the OSHA formaldehyde compliance standard will be required to include annual training for employees who use formalin.

4. Areas identified as exceeding permissible exposure limits must be signed with the following warning:

   DANGER: IRRITANT AND POSSIBLE CANCER HAZARD.
   FORMALDEHYDE AUTHORIZED PERSONNEL ONLY

F. Perchloric acid

1. Do not attempt to heat perchloric acid if you do not have access to a properly functioning perchloric acid fume hood. Perchloric acid can only be heated in a hood specially equipped with a wash down system to remove any perchloric acid residue. The hood should be washed down after each use and it is

preferred to dedicate the hood to perchloric acid use only. No organic material should be stored in the hood containing perchloric acid.

2. Perchloric acid can be stored in a perchloric acid fume hood, only keep the minimum amount necessary for your work. Another acceptable storage site is on a metal shelf or in a metal cabinet away from organic or flammable materials. No more than two 1 lb bottles of perchloric acid should be stored in the laboratory. The bottles should be stored in a glass secondary container to contain any leakage.

3. Do not allow perchloric acid to come in contact with strong dehydrating agents such as sulfuric acid.

4. Do not order or use anhydrous perchloric acid or perchloric acid solutions greater than 70% concentration. These can be unstable at room temperature.

5. Examine perchloric acid periodically, and do not use if the solution has turned brownish. Contact the Safety Office to arrange safe disposal of discolored perchloric acid.

G. Carcinogens

The latest Report on Carcinogens can be found at http://ehis.niehs.nih.gov/roc/toc9.html and contains a listing of known and suspected carcinogens.

1. Use of carcinogens requires the following:

   (a) Designation of specific work areas with restricted access.

   (b) Listing of personnel authorized to work in the area.

   (c) Inventory of types and quantities of reagents on hand.

   (d) Personnel must be trained in safe handling procedures for the specific carcinogenic chemicals used.

   (e) Records of exposure must be maintained.

   (f) Procedures for monitoring storage, decontamination, disposal and emergency procedures must be established.

   (g) Medical surveillance of personnel.

   (h) Protective clothing must be provided.

   (i) Hand washing is required immediately after handling.

H. Allergens, Reproductive Toxins and Highly Hazardous Chemicals.

1. Allergens

(a) Wear suitable protective clothing, gloves or masks to prevent contact with allergens and substances of unknown allergenic activity. (*Consult MSDSs or SDSs in MAXCOM database.*)

2. Reproductive Toxins

(a) Employees must be advised of substances that act as reproductive hazards.

(b) Use should be reviewed for particular hazards by the investigator to see if special procedures are warranted or warning signs should be posted. The investigator should determine if any additional information or monitoring is warranted.

(c) Embryotoxins requiring special control should be stored in a well ventilated area. The container should be labeled in a clear manner such as:

EMBRYOTOXIN: READ SPECIFIC PROCEDURES FOR USE

(d) If the container is breakable, it should be kept in an impermeable, unbreakable secondary container large enough to hold 2x the material in case the primary container leaks or breaks.

(e) Women of childbearing age should take adequate precautions to guard against spills or splashes.

(f) Appropriate apparel (*Consult MSDSs or SDSs in MAXCOM database.*), particularly gloves, should be worn.

(g) All hoods, glove boxes and other essential engineering controls should be inspected for adequate airflow before starting an operation.

(h) Investigators must be notified of all exposures or spills of embryotoxins requiring special control.

3. **Highly Hazardous Chemicals (HHCs)**

(a) HHCs are stored separately from other chemicals, in a designated area where such chemicals will be used. This area should be appropriately marked so that personnel unfamiliar with the laboratory will be informed of the potential hazard.

(b) Special warning signs should be posted such as:

CAUTION: CANCER-SUSPECT AGENT or
CAUTION: HIGH CHRONIC TOXICITY AGENT

(c) Always use a hood, Biological Safety Cabinet or other containment device for all procedures. See **Appendix B** for a list of examples of HHCs.

(d) Wear proper personal protective equipment (PPE) when working with these chemicals. Wash hands immediately after working with these chemicals.

e) Containers should be stored in a ventilated, limited access area in labeled, unbreakable, chemically resistant, secondary containers.

(f) Any contaminated equipment or glassware will be decontaminated in the hood prior to removing them from the designated area.

(g) Maintain records that include the amount of material and names of workers.

(h) If using significant quantities of HHCs on a regular basis, consult a qualified physician concerning regular medical surveillance.

(i) Animal Work with HHCs

(1) Warning signs and safety protocols need to be posted on the animal room door and the cage cards. The name of the agent, hazard, and the name and telephone number of the individual to contact in the event of an emergency involving the agent should be included.

(2) The administration of the HHCs will be by injection or gavage when possible rather than by diet.

(3) When diet is used, a caging system under negative pressure or under laminar airflow directed toward HEPA filters should be used.

(4) Procedures should be followed to reduce aerosolization during removal of contaminated bedding.

(5) Animals receiving HHCs need to be housed separately from other animals.

VII. EXPOSURE CONTROL PLAN

A. The LSC will work with the Safety Office, Principal Investigator and lab managers to develop and implement safety training appropriate to each lab group.

B. Your first line of protection against exposure when working in the lab is: Wearing a lab coat and gloves and washing hands often. Lab coats are obtained from and returned to the VA laundry room.

C. It is the supervisors' responsibility to provide gloves that afford the protection needed. When choosing gloves, it is essential that employees use gloves designed for the hazards, chemicals and tasks found in their workplace. See **Appendix B** for a table of types of gloves protective against specific chemicals.

D. Appropriate gloves should be worn when working in hot or freezing situations. For example:

1. Non-asbestos autoclave gloves are available and should be used to handle hot glassware.

2. Large cryo-protective gloves are available for retrieving liquid nitrogen vials.

E. Wear eye and face protection that properly fits and is appropriate to the work being performed. Some of the most common types of eye and face protection include: safety spectacles, goggles, laser safety goggles and face shields. Wear protective goggles when working with corrosive chemicals, homogenizing samples, using sonicator or when retrieving liquid nitrogen vials. Hazards from vortexing can be minimized by wearing goggles.

F. Wear a UV-protective full-face shield when using the transilluminator.

G. Personal protective equipment (PPE) in the form of lab coats, gloves, goggles or similar eye protection and respirators are available to laboratory workers. The Safety Office will provide guidance in determining what level of protection is required for procedures being performed in the various labs. PIs will be responsible for ensuring that PPE is available and that the workers are trained in use of this equipment.

H. Engineering Controls:

1. Exhausting fume hoods will be checked and certified annually for proper function.
2. Laminar flow /biosafety cabinets will be certified annually.
3. Emergency shower and eyewashes will be installed, repaired and maintained by Engineering. Weekly eyewash inspections will be conducted by PI or Laboratory Director
4. Monthly and annual fire extinguisher inspections will be managed by the Safety Department.
5. Storage rooms/cabinets for flammable chemicals and chained stanchions for pressurized gases will be available for proper chemical storage. The Investigators are responsible for providing proper storage for chemicals kept in their labs.

VIII. BIOSAFETY PRECAUTIONS [see **Appendix C**]

A. When using either the laminar flow or fume hood, work within the back half of the hood so as not to disrupt the laminar flow of air within the hood.

B. Avoid use of needles to disrupt potentially hazardous cell suspensions. Eject tips from mechanical pipettors gently and directly into a receptacle. Needles should never be re-capped and should be disposed of in the sharps container. Self-sheathing needles should be used whenever possible.

C. All human specimens shall be considered potentially infected with hazardous agents. Direct handling of these substances is to be avoided. Gloves, forceps, or other protective guard will be used as appropriate.

D. Decontaminate incubators on a regular basis with soap and water, followed by autoclaving of shelves or spraying and wiping down surfaces with 70% ethanol.

E. Spilled virus, homogenate or other potentially infectious samples must be contained with paper towels and immediately covered with a solution of 10% bleach or HB Quat 25 for 15 minutes. The area should then be thoroughly cleaned with water and the spill reported to the supervisor.

F. Pipettes that have been contaminated with virus or viral products are to be soaked in a 10% bleach solution and drained, before being disposed of in a biohazard bag. Pipettes that contain any potentially biohazardous material are disposed of in red plastic biohazard containers. All red plastic biohazard containers must be covered when not in use. Containers must not be overfilled. Staff should replace containers when they are 2/3 full. Biohazardous waste bags/containers are removed by the facility by Environmental Management staff.

G. The U.V. light within a laminar flow hood will be activated only when there is proper shielding and when there is no danger of excessive exposure to laboratory personnel. Protect skin from exposure to the UV light source. The hood should be cleaned out at the end of each procedure. The surface shall be cleaned with a HB Quat followed by 70% ethanol.

H. Refrigerators, culture incubators and any other place where biohazardous agents are used must be identified with a **BIOHAZARD** sticker.

Animal remains (carcasses) will be handled as biohazardous waste for eventual incineration off-site. As such, these remains will be placed in red bags labeled with the biohazardous symbol. 6 NYCRR Part 364 requires that this type of waste be maintained in a "nonputrescent" (odor-free) state, using refrigeration, when necessary. Thus, the associated red bags will be temporarily stored in the Research Building (20) in a cold room or freezer, as appropriate. These red bags will be kept under refrigeration until they are packaged for transportation and off-site incineration. There is no specific time requirement for removal provided the remains are kept in an odor-free condition; however, it is recommended that these remains be removed within 4 weeks after depositing in cold storage. The transfer of the remains from the cold room or freezer to the Regulated Medical Waste (**RMW**) Processing Area will be coordinated with Research and EMS staff to ensure that the remains are kept odor-free.

For specific guidelines regarding biosafety procedures specific to the VMU, see **APPENDIX M**. "*Safety in the Infectious Disease Suite of the VMU*."

IX. CHEMICAL PROCUREMENT, USE AND STORAGE

A. General

1. No chemical is to be received in the laboratory without a Material Safety Data Sheet (MSDS(or Safety Data Sheet (SDS) unless a current sheet is already in the MAXCOM database.

2. Wear proper personal protective equipment (PPE) when working with all lab chemicals. Refer to the most recent in the MAXCOM database to see what is appropriate.

3. Chemicals should be stored by reactive class (*i.e.*, flammables with flammables, oxidizers with oxidizers). [See **Appendix D**] Incompatible chemicals should not be stored together. Secondary containment tubs may be used to segregate by chemical compatibility. Secondary containment tubs are required for all hazardous chemicals.

4. Stored chemicals should be examined periodically for deterioration and container integrity.

5. Amounts permitted in the laboratory work area should be as small as possible and practical.

6. Every effort should be made to find less hazardous substitutes for more hazardous chemicals.

7. Exposure of chemicals to heat sources or direct sunlight should be avoided.

8. Each lab using Highly Hazardous Chemicals (HHC) [See **Appendix B**] must designate a work area where such chemicals will be used. This area should be appropriately marked so that personnel unfamiliar with the laboratory will be informed of the potential hazard.

9. Non-disposable glassware and equipment that comes into contact with HHC should be appropriately marked, and set-aside for use only when wearing proper PPE.

10. Use absorbent bench coverings to contain incidental spills.

11. Please refer to **Appendix D** for chemical compatibility storage practices. The best storage practice is to have incompatible chemicals in secondary containment and stored in physically separate locations (in other words, not in the same cabinet).

12. Fume hoods should not be used as storage areas for chemicals. It is permissible to designate a portion of the fume hood as a hazardous waste satellite accumulation area (**SAA**).

13. Quantities of flammable liquids greater than 1 gallon if glass and 5 gallons if the container is an approved safety container are stored in flammable cabinets located in each research wing. These areas and laboratory chemical storage cabinets should be inspected semi-annually by the Laboratory Safety

Committee. The inspection should focus on container integrity, proper chemical segregation, and the use of secondary containment. The Research Chemical inventory will be updated on an annual basis by each Principal Investigator and forwarded to the R&D Chemical Hygiene Officer and Safety Manager.

14. Disposal of outdated, unusable or spent chemicals and hazardous waste will be arranged with the Facility Safety Officer, who will pick up the waste at the labs.

15. A hazard determination must be made for all chemicals produced exclusively for the lab's use (*i.e.*, custom synthesized chemicals). All appropriate training, and labeling requirements must be met. MSDS or SDS must be in the MAXCOM database. If the chemical is deemed hazardous it must be stored in a secondary containment tub.

B. Flammables and Explosive Chemicals

1. Flammable liquids in quantities greater than 1.1 gallons (4 liters) must be stored in metal safety cans (as required by National Fire Protection Association Standard 45, Table 7.2.3.2). Small quantities of flammable liquids sufficient for the day's use may be kept out on the open bench in properly labeled containers. Bulk quantities must be stored in approved flammable storage cabinets. Flammables requiring refrigeration must only be stored in explosion-proof refrigerators (such refrigerators should be labeled as being safe to store flammable liquids).

2 Flammables should be stored away from caustics, oxidizing acids and oxidizers.

3. Peroxide-forming chemicals (*e.g.*, diethyl ether and tetrahydrofuran) should be stored in airtight containers in a dark, cool place. Each bottle of flammable chemicals prone to peroxide formation shall be labeled with the date of receipt, the user initials and the date the container was opened. An inspection of the chemical should be performed at monthly intervals. Use or dispose of peroxide-forming chemicals prior to their expiration dates or the time recommended in the National Safety Council document *Recognition and Handling of Peroxidizable Compounds*, whichever is shorter.

4. Cans of ether must be used completely once opened, to avoid peroxide formation. Ether use is restricted to explosion-proof fume hoods. Ether may not be used for anesthesia unless a letter of approval has been issued by the Chair of the R& D Committee. **Appendix E** codifies the policy for use of volatile flammable reagents on this station.

C. Acids

1. Large bottles of acids should be stored on a low shelf or in an acid cabinet in secondary containment.

2. Oxidizing acids are to be segregated from organic acids, flammable and combustible materials.

3. Acids must be separated from strong bases and from active metals such as sodium, magnesium and potassium.

4. Acids must be segregated from chemicals that can generate toxic gases on contact.

5. Spill control pillows or acid neutralizers are available for acid spills.

6. Perchloric acid should only be used in the perchloric acid hood which is equipped with special water wash down capability. No more than two 1 lb bottles of perchloric acid should be stored in the laboratory. No organic material should be stored in the hood containing perchloric acid. Do not allow perchloric acid to come in contact with strong dehydrating agents. Examine perchloric acid periodically, and do not use if the solution has turned brownish. Contact the GEMS Coordinator and/or the Safety Office to arrange safe disposal of discolored perchloric acid.

D. Water-Reactive Chemicals

1. Water-reactive chemicals are to be kept in a cool, dry place.

2. In case of fire, follow the RACE protocol (Rescue staff as necessary, Pull the alarm, Confine the area, and Extinguish. Only use an "ABC fire extinguisher", containing ammonium phosphates.

3. Labeled with NFPA label (with the white square filled in).

E. Oxidizing Chemicals

1. Oxidizing chemicals are to be stored away from flammables, combustibles, and reducing agents (e.g. zinc, alkaline metals).

F. Toxic Compounds

1. Toxic compounds are to be stored according to the nature of the chemical with appropriate security employed where necessary.

2. The Poison Control Center telephone number (1-800-222-1222) should be posted in each laboratory.

X. CHEMICAL SPILL RESPONSE:

A. <u>Emergency Spill or Release</u> - *PLEASE NOTE: This facility does not have an on-site emergency response team for chemical spills. In the event of an emergency spill, external responders would be called upon by the facility's Emergency Manager (x8826) or designee. An Emergency Spill exists under any of the following conditions:*

- A person is injured; or
- The identity of the chemical is unknown; or
- Multiple chemicals are involved; or
- The chemical is highly toxic, highly flammable, or highly reactive; or
- The spill occurs in a public space, such as a corridor; or
- The spill has the potential to spread to other parts of the building, such as through the ventilation system; or
- The clean up procedures are not known or appropriate materials are not readily available; or
- The clean up requires a respirator to be worn and no personnel have been fit-tested or officially trained to use a respirator (including cartridge respirators); or
- The spill may endanger the environment, such as by reaching waterways or outside ground.

1. In the event of an emergency spill or airborne release of a chemical agent in the laboratory, the primary concern is the safety of the employees who might be exposed. **DO NOT attempt to control or clean up an emergency chemical spills.**

2. **Evacuate the area**. Dial x3330 to report a Code Orange in Building 20. Identify the exact location of the spill or release and the hazardous chemical released if known. Follow Code Orange unit specific action (USA) chart procedures for Building 20

   <u>Responses to incidental releases of hazardous substances</u> where the substance can be absorbed, neutralized, or otherwise controlled at the time of the release by employees in the immediate release area, or by maintenance personnel, are not considered emergency responses within the scope of this standard (29 CFR 1910.120). Responses to releases of hazardous substances where there is not potential safety or health hazard are not to be considered emergency responses.

   An <u>incidental release</u> is a release of a hazardous substance which does not pose a significant safety or health hazard to the employees in the immediate vicinity or to the worker cleaning it up, nor does it have the potential to become an emergency. For example, a small amount of a substance considered low in toxicity and released from a valve during a maintenance operation would be considered an incidental release, not an emergency.

3. Similarly, the release of a small quantity of a relatively low toxicity chemical during routine laboratory operation, that can be safety cleaned up by the laboratory personnel without significant health or safety hazard, would be considered an <u>incidental spill</u> and would not constitute an emergency.

4. Qualified laboratory personnel can clean-up incidental spills/releases. This training is covered in the computer based Hazard Communication training module. Incidental

spills should be cleaned up using the MSDS or SDS as guidance available in the MAXCOM database.

B. 1. In the event of a spill or airborne release of a chemical agent in the laboratory, the primary concern is the safety of the employees who might be exposed. The two most likely routes of exposure are skin contact and inhalation. **DO NOT attempt to control or clean up chemical spills unless the spill is limited to an incidental spill or release.**

2. Follow the "**R.A.C.E."** concept:

- **Rescue or remove personnel from the spill area.**

Rescue or remove personnel from the immediate area of the spill (only when it is safe to do so). **DO NOT BECOME A VICTIM YOURSELF**. Exposure to some chemicals may impair your ability to escape the spill area or require the response of a specially trained emergency response team. Emergency medical treatment of victims should begin as soon as they are clear of the area where the chemical was released.

- **Alarm and dial 8826 or "O" to report the spill.**

The dispatcher will initiate an emergency response sequence. Tell your supervisor and other techs in the area that there has been a spill or release, warning them to stay clear of the area to avoid further exposure.

- **Contain the spill, only if safe to do so.**

Contain the chemical from contaminating other areas (only when safe to do so). In the event of a small spill of a non-toxic or low toxicity non-volatile liquid, use the spill control pillows from the spill control kits to prevent spread. Volatile or gas/vapor-producing chemicals pose a potential immediate health threat. Spills occurring within fume hoods can be easily isolated by drawing the sash down to allow the hood to exhaust to protect the workers from gas or vapor exposure. Only facility employees included in the Respiratory Protection Program are authorized to use respiratory protection.

- **Evacuate the area.**

C. Incidental Spill control and Clean-up (general):

1. Never attempt to clean up any spill larger than can be accommodated by the spill kits or those spills that produce noxious or toxic fumes.

2. Wear the appropriate PPE during spill response. Consult the most recently released chemical's MSDS or SDS available in the MAXCOM database.

3. Spills of highly hazardous chemicals can pose significant risk to health and safety both for the user and for those working in the area. Absorption of liquids may be achieved with solid absorbents, spill pads or spill control pillows.

Fumes are best allowed to vent through the fume hoods. Shut off all electrical devices if the material is flammable, and use non-sparking tools.

4. Spills involving acids or caustics can be absorbed with the appropriate neutralizing powders available in the spill control cabinets.

5. Spills involving non-hazardous chemicals (such as buffer salts) should be handled by lab workers. Absorb spill onto pillow, or toweling.

6. Spills involving powder or solids can be contained by wetting a clean absorbent pad and carefully placing it over the area of the spill. Never spray a chemical in powder form with a misting device - this will only generate hazardous particulate aerosol! Wrap the wet powder in the absorbent pad, place in a thick plastic bag along with gloves.

7. Spills outside the designated work area (*e.g.,* on the floor): Use absorbent pillow to control spread of contamination. Working from the outside edges of the spill inward, adsorb liquid on the absorbent pillow. The spill area must be clearly marked to keep traffic away from the area until decontamination can be verified.

8. Contact the Hazardous Materials Manager if hazardous waste has been generated. Notify the R&D Chemical Hygiene Officer if any items are used from the lab spill kits.

D. Radioactive Material spills:

1. All accidents involving radioactive materials must be immediately reported to the Health Physics Office, ext 5226/pager 460-2940 or ext 5225/pager 2682. If the accident is serious in nature and occurs at night, contact VA Police at ext 8747 or 2600.

2. Procedures for decontamination and spill clean up can be found in the Radiation Protection Program Manual, which is available in areas where radioactive materials are used.

XI. WASTE DISPOSAL

A. Always consult the MSDS or SDS available in the MAXCOM database for manufacturer's recommended disposal method.

B. Disposal of liquid wastes through the sewer system must comply with all Federal, State and Local regulations and ordinances. Check with the GEMS Coordinator when in doubt as to whether a chemical can be disposed of via the sewer system.

C Some radioactive materials may be disposed of through the sewer. Authorization must be obtained from the Radiation Safety Office. Disposal must be through an approved "signed" sink, and documentation of such disposal should be made. (disposal date, amount, type of isotope, chemical form).

D. All pipettes, sharps, needles and scalpel blades shall be disposed of in red plastic sharps containers labeled with a "biohazard" sticker. The covers must be kept on the container when not in use. Containers should be disposed of when 2/3 full. Biohazardous waste containers are picked up by the Environmental Management Service.

E. Satellite accumulation areas (**SAAs**) will be established at the point where hazardous waste is generated in the laboratories. The SAAs will serve as **temporary** storage areas for hazardous waste prior to placement in a long-term storage area. The GEMS Coordinator will review the location and configuration of the SAAs to determine that they are appropriate. Signage that identifies each SAA will be posted by respective Research Staff. The following procedures will be followed at each SAA:

1. Each container must be clearly marked with the words **"**Hazardous Waste**"** and the identity of the specific chemical contents. Chemical waste is classified as a **"Characteristic" Hazardous Waste** according to the Resource Conservation and Recovery Act (**RCRA**), when it exhibits one or more of the following:

   - **Ignitability** – Flashpoint less than 60° C (140° F);
   - **Corrosivity** – pH less than or equal to 2 or greater than or equal to 12.5;
   - **Reactivity** – Unstable, can cause explosions or toxic fumes, gases or vapors when heated, compressed or mixed with water;
   - **Toxicity** – Harmful or fatal when ingested or absorbed or released to the environment.

   Additionally, chemical waste may be RCRA "Listed" (F, K, P, or U) Hazardous Waste as defined by 40 CFR Part 261 Subpart D. If you have any questions about whether a chemical waste is a RCRA hazardous waste, contact the GEMS coordinator for a definitive determination.

2. Containers will be sound and compatible with the contents.

3. <u>Containers will remain closed</u> except when adding material.

4. Containers will be stored in secondary containment.

5. Reactive chemicals (*e.g.*, acids and bases, etc.) will be kept segregated from other reactive waste and other material and stored in flammable storage cabinets as necessary.

6. When the container becomes full, or when the waste is no longer generated, contact the GEMS Coordinator for disposal. Multiple types and containers are allowed but each must be labeled as described above. For "Characteristic", "F", "K", and "U-Listed Hazardous Waste", the maximum volume that may be stored at an SAA is 55 gallons. In the case of "P-Listed (acutely toxic) Hazardous Waste," the maximum volume that may be stored at an SAA is 1 quart.

F. Waste from tissue culture procedures, microbiological waste, acrylamide gels and waste containing trace amounts of toxic materials will be bagged in red bags and put in the regulated medical waste containers in each lab.

G. Gels containing ethidium bromide are collected and disposed of as hazardous waste. A container for these wastes is located in room B626.

H. Unlabeled containers of chemicals and solutions should undergo prompt disposal, with notification to the safety office. If partially used, they should not be opened to identify the contents.

I. Radioactive waste disposal will be coordinated through the Health Physics Office ext 5226 or 5225, and accomplished in accordance with an approved protocol and the Radiation Protection Program Manual.

XII. Use of Laboratory Hoods and Lab Equipment Safety

A. All laboratories will have airflow balanced to be negative with respect to the corridors. Within the labs, the airflow should be balanced positive with respect to the outside exhausting fume hoods. This will create a net flow of air away from the corridor and out the fume hoods. Airflow within the laboratory should be relatively uniform with no turbulent, static or high velocity areas.

B. All exhausting fume hoods and Biosafety (laminar flow) cabinets will be monitored for proper operation before use. The acceptable velocity range for a lab fume hood is 80 – 120 feet/minute. Hood sashes should be marked to indicate appropriate working heights. Laminar flow hoods are equipped with magnehelic gauges to record the performance of the HEPA filters. Hood users should be familiar with the proper range of readings for the magnehelic so they may detect deteriorating performance of the hood filters. All hoods and cabinets will be checked and certified by an outside contractor annually. **Before starting work in a fume hood**, check that the hood is working properly by observing flutter strip for movement and direction of flow. If a hood fails, close the sash and call Facilities Management at ext 5546. Do not use the hood until it has been checked out and repaired.

C. Be sure any safety shields, filters, or similar devices are present on laboratory equipment before operating. Keep all laboratory machinery in good repair. Examine all electrical equipment frequently for worn or broken wires and take all such defective items out of service until they can be repaired. If defective or inoperable laboratory equipment is found, please notify the Biomedical Engineering Dept. for repair. Provide proper ventilation for any equipment that emits hazardous or noxious fumes (Ex: ozone produced by some types of spectrophotometer lamps).

D. Avoid placing heat sources (Bunsen burners, hot plates, etc.) in the same area where flammable materials or chemicals will be handled. Do not leave heating elements, etc. operating and unattended in the lab. Electrophoresis equipment is an exception. This, however, should be double-checked before leaving the equipment running over night.

E. Wherever possible, try to use plastic rather than glass for vessels, storage containers and pipettes, to reduce the possibility of breakage and injury.

F. When centrifuging, inspect tubes before and after use. When centrifuging hazardous or biohazardous materials, the post-centrifugation inspection should be conducted in a fume hood. Wear personal protective equipment, such as gloves, mask, face shield, and lab coat, and exercise care when opening tubes containing hazardous material, to avoid spills or aerosol formation. If a sample leak occurs within a centrifuge, make sure it is adequately cleaned up and sanitized for future operations.

XIII. EXPOSURE MONITORING

It is the policy of this Medical Center to monitor chemical exposures to ensure staff is not exposed to concentrations of contaminants in excess of the Permissible Exposure Limit (**PEL**) and in compliance with OSHA regulations. For some substances, exposure limits published by organizations such as the American Conference of Government Industrial Hygienist (**ACGIH**) may also be used.

The Safety Office is the initial point of contact for such monitoring. Contact Safety Office for details.

The Supervisor is charged with the responsibility for contacting the Safety Office concerning possible chemical over-exposures for which monitoring may be appropriate. Initial monitoring must be conducted in response to several OSHA substance specific standards (*e.g.*, formaldehyde) and where there is reason to believe unhealthy exposures may occur. Monitoring may need to be repeated each time there is a change in procedure, equipment, personnel or control measures such that an increased exposure is suspected.

Employees and their supervisors will be notified of the results within 15 days of Safety Office receipt. Monitoring results will also be provided to Employee Health when measured concentration(s) are greater than or equal to the Threshold Limit Value (**TLV**).

If the employee exposure is found to be over the permissible exposure limit, the employee should NOT continue to perform that work which produced the exposure until control measures can be put in place to reduce the exposure to less than the permissible exposure limit. If control measures are not effective, at reducing the exposure to a level below the permissible exposure limit, the employee must be provided with sufficient personal protective equipment to minimize their exposure.

XIV. RADIATION EXPOSURE AND MONITORING

Employees shall follow all safety procedures and guidelines noted in the Radiation Protection Program Manual and as defined in the initial "Non-Human Use" radioactive material application submitted to the Radiation Safety Committee and in subsequent correspondence from the Radiation Safety Committee to the Authorized User. Employees contaminated by radioactive materials will follow the procedures outlined in

the Radiation Protection Program Manual, with regard to proper response, reporting and investigation of the incident. All exposures will follow guidelines in the Radiation Protection Program Manual.

Radiation exposure is monitored monthly or quarterly through the use of radiation dosimetry and in some cases bioassay measurements. Monitoring requirements are specified in the Radiation Protection Program Manual, which should be maintained and made available in each area where radioactive materials are in use. Monitoring requirements may also be defined in the initial "Non-Human Use" radioactive material application submitted to the Radiation Safety Committee and in subsequent correspondence from the Radiation Safety Committee to the Authorized User. The Radiation Protection Program Manual is also available from the Health Physics Office, ext 5226 or 5225.

XV. HOUSEKEEPING, MAINTENANCE AND INSPECTIONS

A. Housekeeping

1. Environmental Management Service is responsible for routinely cleaning all floors within Research Service areas.

2. All Research personnel are responsible for cleaning of all bench tops and other work areas such as fume hoods and laminar flow hoods

3. EMS does not respond to chemical spills

B. Maintenance

1. Biomedical Engineering Service is responsible for all routine maintenance on laboratory equipment except for those pieces that are covered by a maintenance contract.

2. Biomedical Engineering coordinates the inspection, cleaning and certification of all laminar flow hoods and fume hoods on a yearly basis. Staff will not use hoods lacking certification or where certification has expired.

3. Eye wash stations will be inspected on a weekly basis by the laboratory staff. Any problems will be reported to Engineering. Interim safety measures will be used in the event of malfunctions.

4. Emergency drench-type showers will be maintained by Engineering.

5. Fire Extinguishers inspections will be managed by the Safety Department on a monthly basis. Discharged or non-operational extinguishers will be reported to the Safety Officer.

C. Inspections

1. Members of the Environment of Care Committee will perform a formal inspection of Research areas two time per year.

2. Members of the SRS will perform an annual inspection of Research areas.

D. Passageways

1. Stairwells and hallways will not be used as storage areas.

2 Access to emergency exits, emergency equipment and utility controls will never be blocked.

3. Emergency exit routes will be posted**.**

XVI. BLOOD BORNE PATHOGENS

All Blood Borne Pathogens (**BBP**) activities are required to refer to blood borne pathogen policy and staff is strongly encouraged to receive the Hepatitis B Vaccine.

XVII. MEDICAL SURVEILLANCE

The Employee Health Physician administers the medical surveillance programs, as outlined by OSHA regulations, for all employees who handle or are exposed to hazardous materials.

A. The following are monitored by the Medical Center Safety Office:

Formaldehyde	Noise
Ionizing Radiation	Nitrous Oxide
Blood-borne disease agents	Ethylene Oxide
Heat (Ambient Temperature)	Chemotherapeutic Agents
Asbestos	Anticholinesterases/insecticide

B. All employees who work with hazardous chemicals will receive medical attention, including follow-up examinations when necessary, under the following circumstances:

1. Whenever an employee develops signs and symptoms associated with exposure to a hazardous chemical to which the employee may have been exposed in the laboratory, the employee shall be provided an opportunity to receive an appropriate medical examination.

2. Where exposure monitoring reveals an exposure level routinely above the **action** level (or in the absence of an action level, the Permissible Exposure Limit (PEL)) for an OSHA level regulated substance for which there are exposure monitoring and medical surveillance requirements, a medical surveillance shall be established for the affected employee as prescribed by the particular standard.

3. Whenever an event takes place in the work area such as a spill, leak explosion or other occurrence resulting in the likelihood of a hazardous exposure, the affected employee shall be provided an opportunity for medical consultation. Such consultation shall be for the purpose of determining the need for medical examination.

4. All medical examination and consultations shall be performed by or **u**nder the direct supervision of a licensed physician and shall be provided without cost to the employee, without loss of pay and at a reasonable time and place.

C. Information provided to the physician

The employer shall provide the following information to the physician:

1. The identity of the hazardous chemical to which the employee may have been exposed.

2. Description of the conditions under which the exposure occurred, including quantitative exposure data, if available.

3. Description of the signs and symptoms the employee is experiencing, if any.

D. Physician's written opinion.

1. For examination or consultation, the employer shall obtain a written opinion from the examining physician which shall include the following:

   (a) Any recommendation for further medical follow-up.

   (b) Results of the medical examination and any associated tests.

   (c) Any medical condition, which may be revealed in the course of the examination which may place the employee at increased risk as a result of exposure to a hazardous workplace.

   (d) A statement that the employee has been informed by the physician of the results of the consultation or medical examination and any medical condition that may require further examination or treatment.

   (e) The written opinion shall not reveal specific finding of diagnoses unrelated to occupational exposure.

XVIII. EMERGENCY FIRST AID PROCEDURES

All injuries must be reported to your immediate supervisor. After taking emergency steps recommended below, medical attention should be obtained from Employee Health or the Emergency Physician. In accordance with medical center policy, a supervisor must accompany the employee to the Employee Health Unit**.** If the injury involves radioisotopes, the RSO should also be notified. The accident should be documented.

A. Eye Contact

1. In the event of a chemical splash to the eyes, ask co-workers to help you wash the eyes thoroughly using the nearest eye wash station. Lift eyelids to avoid pooling of chemicals under the eyelids. Continue to flush the eyes using an eyewash bottle while co-workers escort the injured employee to the Emergency Department.

2. Seek medical attention from Employee Health or the Emergency Room immediately and ensure that a copy of the MSDS or SDS is provided to the medical caregiver. MSDS and SDS are available in the MAXCOM database.

B. Skin contact

1. Corrosives can cause second or third degree burns. These chemicals include alkalis such as sodium hydroxide and common acids such as hydrochloric, sulfuric and nitric.

2. Chemicals should be diluted and washed off with copious amounts of water. Minor splashes and spills can be flooded in a sink. Larger splashes and spills require the use of the emergency drench-type shower. Showers are located in Rooms 230 and 123. Enlist the help of co-workers. Some chemical powders should be brushed off the skin before flooding with water to avoid further skin and tissue damage. Always consult the MSDS or SDS for emergency first aid procedures BEFORE working with any chemical. MSDS and SDS are available in the MAXCOM database.

C. Inhalation

1. Move personnel to fresh air, and seek medical attention in Employee Health or the Emergency Department.

D. Ingestion

1. Seek medical attention in Employee Health or the Emergency Department.

E. Radiation Contamination

1. Employees contaminated by radioactive materials will follow the procedures outlined in the Radiation Protection Program Manual.

2. The Radiation Safety Officer (**RSO**) is to be notified immediately if personnel contamination occurs. A written report is to be filed with the Health Physics Office as described in the Radiation Protection Program Manual. A copy of this record should be kept in the Radiation Safety records in the lab as well.

XIX. PROTECTIVE APPAREL AND EQUIPMENT

Personal Protective Equipment (PPE) includes gloves, goggles, face shields, aprons, fluid resistant/impervious gowns, masks and respirators. Although the use of such equipment is generally the least desirable way to control workplace hazards, because it places the burden of protection on the worker, the equipment must be available for situations when an unexpected exposure to chemical substances, physical agents or biological materials could have serious consequences.

The Medical Center Safety and Health Office may be called upon for guidance in selection of PPE.

A. Types of Personal Protective Equipment

1. General

   (a) Protective apparel must be compatible with the required degree of protection for the substances being handled.

   (b) Emergency eyewash stations are available in labs that are meet the requirements for an eyewash station in accordance CM00-174, Emergency Shower and Eyewash Program. Bulk acids and bases with potential for splashing staff will be handled in two areas, Room 230 and 123. These rooms are equipped with emergency drench showers. .

   (c) A fire extinguisher is located in each laboratory.

2. Eye

   (a) Chemical splash goggles and/or face shields, RATHER than safety glasses, should be used when pouring any hazardous chemicals, as they have been proven to be the best protection. Safety glasses provide only minimal splash protection.

   (b) Protective eyewear must be available in all areas where hazardous substances are utilized.

   (c) Protective eyewear should be easy to clean and disinfect.

   (d) For those employees who wear glasses, goggles must fit over the glasses. Prescription lenses can often be incorporated into protective eye wear.

3. Gloves

   (a) Gloves (latex, vinyl or nitrile) will be provided for all employees. Appropriate gloves should be worn for the specific hazard **Appendix F.**

B. Other Personal Protective Equipment

1. Rubber, acid-resistant aprons should be worn when pouring concentrated chemicals.

2. Respirators: Follow the Facilities Respirator Protection Program

   (a) Respirators must be chosen as to the hazard for which they are intended.

   (b) The Medical Center Safety Office administers this respirator program.

XX. RECORD KEEPING

A. Accident Reporting (electronically):

1. Supervisor must take the employee to Employee Health. The supervisor must complete VA Form 2162, Report of an Accident.

2. The Safety Office will present all accident data to the Accident Review Board.

3. All employee-related incidents, in which there is even a remote possibility of **employee** overexposure, should be thoroughly investigated in accordance with this plan. Events or circumstances which might reasonably constitute overexposure include:

   (a) A hazardous chemical leaked, spilled or otherwise rapidly released in an uncontrolled manner.

   (b) A laboratory employee has direct skin or eye contact with a hazardous material.

   (c) A laboratory employee manifests symptoms such as headache, rash, nausea, coughing, tearing, irritation or redness of the eyes, irritation of the nose to throat, dizziness, loss of motor dexterity or judgment, etc. and (i) some or all of the symptoms disappear when the person is taken away from the exposure area and breathes fresh air, and (ii) the symptoms reappear soon after the employee returns to the work with the same hazardous chemical.

4. All complaints and their dispositions, no matter what the ultimate dispositions are, must be documented. If no further assessment of the event is deemed necessary, the reason for that decision should be included in the documentation. If the decision is to investigate, a formal Exposure assessment will be initiated.

B. Medical Record Keeping:

1. Medical records will be retained by Employee Health.

C. Chemical Exposure Monitoring:

1. Records will be maintained by the Medical Center Safety Office. Results are communicated to the employee, employee's supervisor and if appropriate, the Employee Health Office.

D. Fume Hood Testing/Maintenance Records:

1. Engineering coordinates testing of all fume hoods. The date of certification will be applied to the fume hood and a copy of the results of testing forwarded to the Research Office, where they will be kept on file for a minimum of 2 years. Copies of fume hood records will be provided to the affected service.

E. Chemical Inventory:

1. Each laboratory will maintain a complete inventory of all chemicals utilized by each investigator. All inventories should contain the chemical name, location of storage, quantity and chemical manufacturer. A copy of the complete chemical inventory will be sent to the Medical Center Safety Office on a yearly basis.

2. An MSDS or SDS for each chemical will be maintained in each laboratory and be readily accessible to employees that may come into contact with the chemical. A copy of each new MSDS or SDS received, should be loaded into the MAXCOM database.

XXI. SIGNS AND LABELS

A. Signs to be Posted Prominently

1. Telephone numbers of emergency personnel, supervisors and laboratory workers.

2. Location signs for eyewash stations and other safety and first aid equipment.

3. Location of emergency exits.

4. Location of spill kits.

5. Location of MSDS or SDS. Desktop shortcut for access to the MAXCOM database.

6. Warnings at areas where unusual hazards exist, such as x-ray equipment, lasers, etc.

7. "Caution - Radioactive Materials" signage (which contains a summary of general safety rules, a emergency procedure summary and Health Physics Office contact information) and a "NRC Form #3" sign will be posted on all entrances to radioactive material use areas.

B. Chemical Labeling:

1. Each chemical container must be labeled with the following information:

   (a) Chemical identity, abbreviations will not be accepted. Complete names are required; *e.g.*, "Ethyl Alcohol" or "Ethanol", not "EtOH".

   (b) Appropriate Hazard (*i.e.*, caustic, corrosive, poison, irritant, flammable, carcinogen, etc.)

(c) Date received.

(d) Date opened.

(e) Expiration date, if any.

(f) Any special storage requirements.

XXII. EMPLOYEE INFORMATION AND TRAINING

Prior to assignment where hazardous chemicals are present, employees will be provided with information and training regarding the hazards of chemicals in their work area, by their supervisor. Training updates and new safety information will be made available at research staff meetings and at annual reviews.

A. Information provided to all new employees:

1. Contents of laboratory standard. (see **Appendix A** *Biosafety in Microbiological and Recombinant DNA Laboratories*.)

2. The Chemical Hygiene Plan (CHP) will be readily available to all employees and students. A copy of the CHP will be available in each laboratory as well as the Research Service Office.

3. OSHA permissible exposure limits or the American Conference of Governmental Industrial Hygienists TLV limits.

4. Signs and symptoms associated with exposure to hazardous chemicals used in the laboratory.

5. Location and availability of reference materials on hazards and safe handling storage and disposal of hazardous substances, in addition to MSDS or SDS. MSDS and SDS are available in the MAXCOM database.

6. Contacting Employee Health in the event of an accident or exposure to a hazardous substance.

B. Training provided to employees

1. Personnel with a potential for exposure to hazardous substances will be trained in the safe handling practices to avoid exposure. Principal Investigators bear the primary responsibility to ensure that proper training is provided and explained to all employees on all shifts

2. Before beginning work in the laboratory, personnel will receive initial training in laboratory safety and the OSHA Laboratory Standard. This training is administered by the Research Office and/or RCHO and includes:

    (a) Methods and observations utilized to detect the presence and release of hazardous chemicals to include continuous monitoring devices and visual appearance or odor of hazardous chemicals when being released.

    (b) The physical and health hazards of chemicals in the laboratory.

    (c) Measures employees can take to protect themselves from chemical and radiation exposure by following emergency procedures and using proper personal protective equipment.

    (d) Spill clean up.

    (e) Signs and symptoms associated with chemicals utilized by the Research Service.

    (f) Safe handling and disposal of hazardous materials.

C. Mandatory Annual Training

1. Training as required by the Medical Center Safety Office and the Health Physics Office.

D. Modes of Training

1. All training records pertaining to what is described under the "Employee Information and Training" section shall be properly maintained to include as a minimum:

    (a) Training content.

    (b) Employee attendance, signature.

    (c) Date(s) of training.

2. Training content and effectiveness shall be fully documented and communicated to the facility Environment of Care Committee in accordance with the Joint Committee on Accreditation of Health Care Organizations (JCAHO) requirements.

APPENDIX A
BIOSAFETY IN MICROBIOLOGICAL AND RECOMBINANT DNA LABORATORIES

A. Responsibility of the Principal Investigator

The Principal Investigator is responsible for complying fully with the Guidelines in conducting any recombinant DNA research. As part of general responsibility the PI shall:

1. Laboratory work cannot commence without prior approval of the Committees required by VA and NIH guidelines.

2. Be adequately trained in good microbiological techniques.

3. Instruct and train staff in the practices and techniques required to ensure safety and in the procedures for dealing with accidents.

4. Supervise the safety performance of the staff to ensure that the required safety practices and techniques are employed.

5. Investigate and report in writing to the Committee and the Research Safety Officer any significant problems pertaining to the operation and implementation of containment practices and procedures.

6. Correcting work error conditions that may result in the release of recombinant DNA materials.

B. Establishment of a Designated Area

In general, procedures involving microorganisms or recombinant DNA will be performed in the individual Investigator's laboratories.

C. Use of Containment Devices and Personal Protection Equipment

1. For any use where the potential exists for spillage of liquid microbiological culture, the bench should be covered with blue absorbent cloth.

2. When manipulating liquid cultures, eye protection should be worn, if eyeglasses are not.

3. A lab coat must be worn at all times.

4. Gloves must be worn at all times.

5. Bench top must be washed with any commercially available germicide such as 70% ethanol at the completion of procedures involving live organisms.

D. Procedure for Safe Removal of Contaminated Waste

1. Add a liquid disinfectant (bleach, ethanol, iodine) to liquid cultures. Let solution sit at room temperature for 10 minutes. Dispose of decontaminated liquid directly into drain in which water is already running. Flush drain with additional water.

2. Soak any non-disposable glassware in fresh 10% bleach for 10 minutes and rinse thoroughly with water before washing as usual.

3. Contaminated disposable glassware, plastics and other supplies must be contained in a red bag in a Biohazard containment can located in each laboratory. These bags will be disposed of by EMS.

4. Rotors used for centrifuging liquid culture material must be soaked in dilute 7X detergent for 10 minutes and rinsed thoroughly with tap, then Nanopure water and air-dried. If a spill has occurred in the rotor, follow **Decontamination Procedures** below.

5. Culture plates containing live organisms must be autoclaved for 20 minutes or disposed of in red bags, for incineration. After autoclaving, date and label with autoclave tape "Rendered Harmless" before disposal.

E. Decontamination Procedures

1. Anytime a spill has occurred, the area must be decontaminated with 10% bleach for 10 minutes. This includes the interior of the shaking incubators, spills inside rotors and centrifuges and bench tops.

2. Following the application of bleach, the area must be thoroughly flooded with water and dried to avoid rusting.

3. If a contamination occurs which cannot be corrected, such as contamination or potential contamination of another person's experiment or contamination of equipment, which cannot be cleaned, the Safety committee must be notified.

F. Recombinant DNA Experiment Classification Guidelines

1. Non-exempt recombinant DNA experiments require oversight by the following:

    a. NIH Office of Biotechnology activities (OBA): This NIH office has responsibility for reviewing and coordinating all activities of NIH relating to the Guidelines.

    b. Recombinant DNA Advisory Committee (RAC): The public advisory committee that advises the Secretary, the Assistant Secretary for Health, and the Director, NIH, concerning recombinant DNA research.

    c. VA Subcommittee on Research Safety and the SUNY at Buffalo Biosafety Committee.

2 . NIH-defined experimental guidelines are listed below.

Section III-A. Experiments that Require SRS Approval, RAC Review, and NIH Director Approval Before Initiation

Section III-A-1. Major Actions under the *NIH Guidelines*
Experiments considered as *Major Actions* under the *NIH Guidelines* cannot be initiated without submission of relevant information on the proposed experiment to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax), the publication of the proposal in the *Federal Register* for 15 days of comment, review by RAC, and specific approval by NIH. The containment conditions or stipulation requirements for such experiments will be recommended by RAC and set by NIH at the time of approval. Such experiments require SRS approval before initiation. Specific experiments already approved are included in Appendix D, *Major Actions Taken under the NIH Guidelines*, which may be obtained from the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax).

Section III-A-1-a. The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally (see NIH guidelines Section V-B, *Footnotes and References of Sections I-IV*), if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture, will be reviewed by RAC.

Section III-B. Experiments That Require NIH/OBA and SRS Approval Before Initiation

Experiments in this category cannot be initiated without submission of relevant information on the proposed experiment to NIH/OBA. The containment conditions for such experiments will be determined by NIH/OBA in consultation with *ad hoc* experts. Such experiments require SRS&B approval before initiation (see NIH Guidelines Section IV-B-2-b-1., *Institutional Biosafety Committee*).

Section III-B-1. Experiments Involving the Cloning of Toxin Molecules with LD50 of Less than 100 Nanograms per Kilogram Body Weight. Deliberate formation of recombinant DNA containing genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight (*e.g.*, microbial toxins such as the botulinum toxins, tetanus toxin, diphtheria toxin, and *Shigella dysenteriae* neurotoxin). Specific approval has been given for the cloning in *Escherichia coli* K-12 of DNA containing genes coding for the biosynthesis of toxic molecules, which are lethal to vertebrates at 100 nanograms to 100 micrograms per kilogram body weight. Specific experiments already approved under this section may be obtained from the Office of Biotechnology Activities (**OBA**), National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax).

Section III-C. Experiments that Require SRS and Institutional Review Board Approvals and RAC Review Before Research Participant Enrollment

Section III-C-1. Experiments Involving the Deliberate Transfer of Recombinant DNA, or DNA or RNA Derived from Recombinant DNA, into One or More Human Research Participants. For an experiment involving the deliberate transfer of recombinant DNA, or DNA or RNA derived from recombinant DNA, into human research participants (human gene transfer), no research participant shall be enrolled (see definition of enrollment in Section I-E-7) until the RAC review process has been completed (see NIH Guidelines, Appendix M-I-B, *RAC Review Requirements*).

In its evaluation of human gene transfer proposals, the RAC will consider whether a proposed human gene transfer experiment presents characteristics that warrant public RAC review and discussion (See NIH Guidelines, Appendix M-I-B-2). The process of public RAC review and discussion is intended to foster the safe and ethical conduct of human gene transfer experiments. Public review and discussion of a human gene transfer experiment (and access to relevant information) also serves to inform the public about the technical aspects of the proposal, meaning and significance of the research, and any significant safety, social, and ethical implications of the research.

Public RAC review and discussion of a human gene transfer experiment may be: 1. initiated by the NIH Director; or 2. initiated by the NIH OBA Director following a recommendation to NIH OBA by: (a) three or more RAC members; or (b) a Federal agency other than NIH. After a human gene transfer experiment is reviewed by the RAC at a regularly scheduled meeting, NIH OBA will send a letter, unless NIH OBA determines that there are exceptional circumstances, within 10 working days to the NIH Director, the Principal Investigator, the sponsoring institution, and other DHHS components, as appropriate, summarizing the RAC recommendations.

For a clinical trial site that is added after the RAC review process, no research participant shall be enrolled (see definition of enrollment in NIH Guidelines, Section I-E-7) at the clinical trial site until the following documentation has been submitted to NIH OBA:

1. SRS approval (from the clinical trial site);
2. Institutional Review Board approval;
3. Institutional Review Board-approved informed consent document;
4. Curriculum vitae of the principal investigator(s) (no more than two pages in biographical sketch format); and
5. NIH grant number(s) if applicable.

In order to maintain public access to information regarding human gene transfer protocols (including protocols that are not publicly reviewed by the RAC), NIH OBA will maintain the documentation described in NIH Guidelines, Appendices M-I through M-V. The information provided in response to Appendix M should not contain any confidential commercial information or trade secrets, enabling all aspects of RAC review to be open to the public.

Note: For specific directives concerning the use of retroviral vectors for gene delivery, consult NIH Guidelines, Appendix B-V-1, *Murine Retroviral Vectors.*

Section III-D. Experiments that Require SRS Approval Before Initiation

Prior to the initiation of an experiment that falls into this category, the Principal Investigator must submit a registration document to the SRS which contains the following information: (i) the source(s) of DNA; (ii) the nature of the inserted DNA sequences; (iii) the host(s) and vector(s) to be used; (iv) if an attempt will be made to obtain expression of a foreign gene, and if so, indicate the protein that will be produced; and (v) the containment conditions that will be implemented as specified in the *NIH Guidelines*. For experiments in this category, the registration document shall be dated, signed by the Principal Investigator, and filed with the SRS. The SRS shall review and approve all experiments in this category prior to their initiation. Requests to decrease the level of containment specified for experiments in this category will be considered by NIH (see NIH Guidelines, Section IV-C-1-b-2.-I, *Minor Actions*).

Section III-D-1. Experiments Using Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents as Host-Vector Systems (See NIH Guidelines, Section II-A, Risk Assessment)

Section III-D-1-a. Experiments involving the introduction of recombinant DNA into Risk Group 2 agents will usually be conducted at Biosafety Level (BL) 2 containment. Experiments with such agents will usually be conducted with whole animals at BL2 or BL2-N (Animals) containment.

Section III-D-1-b. Experiments involving the introduction of recombinant DNA into Risk Group 3 agents will usually be conducted at BL3 containment. Experiments with such agents will usually be conducted with whole animals at BL3 or BL3-N containment. No BL3 laboratories exist in this facility.

Section III-D-1-c. Experiments involving the introduction of recombinant DNA into Risk Group 4 agents shall be conducted at BL4 containment. Experiments with such agents shall be conducted with whole animals at BL4 or BL4-N containment. No BL4 laboratories exist in this facility

Section III-D-1-d. Containment conditions for experiments involving the introduction of recombinant DNA into restricted agents shall be set on a case-by-case basis following NIH/OBA review. A U.S. Department of Agriculture permit is required for work with plant or animal pathogens (see NIH Guidelines, Section V-G and V-M, *Footnotes and References of Sections I-IV*). Experiments with such agents shall be conducted with whole animals at BL4 or BL4-N containment. No BL4 laboratories exist in this facility.

Section III-D-2. Experiments in Which DNA From Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems

Section III-D-2-a. Experiments in which DNA from Risk Group 2 or Risk Group 3 agents (see NIH Guidelines, Section II-A, *Risk Assessment)* is transferred into nonpathogenic prokaryotes or lower eukaryotes may be performed under BL2 containment. Experiments in which DNA from Risk Group 4 agents is transferred into nonpathogenic prokaryotes or lower eukaryotes may be performed under BL2 containment after demonstration that only a totally and irreversibly defective fraction of the agent's genome is present in a given recombinant. In the absence of such a demonstration, BL4 containment shall be used. The Institutional Biosafety Committee

may approve the specific lowering of containment for particular experiments to BL1. Many experiments in this category are exempt from the *NIH Guidelines* (see Section III-F, *Exempt Experiments*). Experiments involving the formation of recombinant DNA for certain genes coding for molecules toxic for vertebrates require NIH/OBA approval (see Section III-B-1, *Experiments Involving the Cloning of Toxin Molecules with LD*50 *of Less than 100 Nanograms Per Kilogram Body Weight*) or shall be conducted under NIH specified conditions as described in NIH Guidelines, Appendix F, *Containment Conditions for Cloning of Genes Coding for the Biosynthesis of Molecules Toxic for Vertebrates*.

Section III-D-2-b. Containment conditions for experiments in which DNA from restricted agents is transferred into nonpathogenic prokaryotes or lower eukaryotes shall be determined by NIH/OBA following a case-by-case review (see NIH Guidelines, Section V-L, *Footnotes and References of Sections I-IV*). A U.S. Department of Agriculture permit is required for work with plant or animal pathogens (see NIH Guidelines, Section V-G, *Footnotes and References of Sections I-IV*).

Section III-D-3. Experiments Involving the Use of Infectious DNA or RNA Viruses or Defective DNA or RNA Viruses in the Presence of Helper Virus in Tissue Culture Systems Caution: Special care should be used in the evaluation of containment levels for experiments, which are likely to either, enhance the pathogenicity (e.g., insertion of a host oncogene) or to extend the host range (e.g., introduction of novel control elements) of viral vectors under conditions that permit a productive infection. In such cases, serious consideration should be given to increasing physical containment by at least one level.
Note: Recombinant DNA or RNA molecules derived therefore, which contain less than two-thirds of the genome of any eukaryotic virus (all viruses from a single Family (see NIH Guidelines, Section V-J, *Footnotes and References of Sections I-IV*) being considered identical (see NIH Guidelines, Section V-K, *Footnotes and References of Sections I-IV*), are considered defective and may be used in the absence of helper under the conditions specified in Section III-E-1, *Experiments Involving the Formation of Recombinant DNA Molecules Containing No More than Two-Thirds of the Genome of any Eukaryotic Virus*.

Section III-D-3-a. Experiments involving the use of infectious or defective Risk Group 2 viruses (see NIH Guidelines, Appendix B-II, *Risk Group 2 Agents*) in the presence of helper virus may be conducted at BL2.

Section III-D-3-b. Experiments involving the use of infectious or defective Risk Group 3 viruses (see NIH Guidelines, Appendix B-III-D, *Risk Group 3 (RG3) – Viruses and Prions*) in the presence of helper virus may be conducted at BL3. No BL3 laboratories exist in this facility.

Section III-D-3-c. Experiments involving the use of infectious or defective Risk Group 4 viruses (see NIH Guidelines, Appendix B-IV-D, *Risk Group 4 (RG4) – Viral Agents*) in the presence of helper virus may be conducted at BL4. No BL4 laboratories exist in this facility

Section III-D-3-d. Experiments involving the use of infectious or defective restricted poxviruses (see NIH Guidelines, Sections V-A and V-L, *Footnotes and References of Sections I-IV*) in the presence of helper virus shall be determined on a case-by-case basis

following NIH/OBA review. A U.S. Department of Agriculture permit is required for work with plant or animal pathogens (see NIH Guidelines, Section V-G, *Footnotes and References of Sections I-IV*).

Section III-D-3-e. Experiments involving the use of infectious or defective viruses in the presence of helper virus, which are not covered in Sections III-D-3-a through III-D-3-d may be conducted at BL1.

Section III-D-4. Experiments Involving Whole Animals

This section covers experiments involving whole animals in which the animal's genome has been altered by stable introduction of recombinant DNA, or DNA derived therefore, into the germ-line (transgenic animals) and experiments involving viable recombinant DNA-modified microorganisms tested on whole animals. For the latter, other than viruses, which are only vertically transmitted, the experiments may *not* be conducted at BL1-N containment. A minimum containment of BL2 or BL2-N is required.
Caution – Special care should be used in the evaluation of containment conditions for some experiments with transgenic animals. For example, such experiments might lead to the creation of novel mechanisms or increased transmission of a recombinant pathogen or production of undesirable traits in the host animal. In such cases, serious consideration should be given to increasing the containment conditions.

Section III-D-4-a. Recombinant DNA, or DNA or RNA molecules derived therefore, from any source except for greater than two-thirds of eukaryotic viral genome may be transferred to any non-human vertebrate or any invertebrate organism and propagated under conditions of physical containment comparable to BL1 or BL1-N and appropriate to the organism under study (see NIH Guidelines, Section V-B, *Footnotes and References of Sections I-IV*). Animals that contain sequences from viral vectors, which do not lead to transmissible infection either directly or indirectly as a result of complementation or recombination in animals, may be propagated under conditions of physical containment comparable to BL1 or BL1-N and appropriate to the organism under study. Experiments involving the introduction of other sequences from eukaryotic viral genomes into animals are covered under Section III-D-4-b, *Experiments Involving Whole Animals*. For experiments involving recombinant DNA-modified Risk Groups 2, 3, 4, or restricted organisms, see NIH Guidelines, Sections V-A, V-G, and V-L, *Footnotes and References of Sections I-IV*. It is important that the investigator demonstrate that the fraction of the viral genome being utilized does not lead to productive infection. A U.S. Department of Agriculture permit is required for work with plant or animal pathogens (see NIH Guidelines, Section V-G, *Footnotes and References of Sections I-IV*).

Section III-D-4-b. For experiments involving recombinant DNA, or DNA or RNA derived therefore, involving whole animals, including transgenic animals, and not covered by Sections III-D-1, *Experiments Using Human or Animal Pathogens (Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents as Host-Vector Systems*, or III-D-4-a, *Experiments Involving Whole Animals*, the appropriate containment shall be determined by the SRS.

Section III-D-4-c. Exceptions under Section III-D-4, *Experiments Involving Whole Animals*

Section III-D-4-c-1. Experiments involving the generation of transgenic rodents that require BL1 containment are described under Section III-E-3, *Experiments Involving Transgenic Rodents*.

Section III-D-4-c-2. The purchase or transfer of transgenic rodents is exempt from the *NIH Guidelines* under Section III-F, *Exempt Experiments* (see NIH Guidelines, Appendix C-VI, *The Purchase or Transfer of Transgenic Rodents*).

Section III-D-5. Experiments Involving Whole Plants

Experiments to genetically engineer plants by recombinant DNA methods, to use such plants for other experimental purposes (e.g., response to stress), to propagate such plants, or to use plants together with microorganisms or insects containing recombinant DNA, may be conducted under the containment conditions described in Sections III-D-5-a through III-D-5-e. If experiments involving whole plants are not described in Section III-D-5 and do not fall under Sections III-A, III-B, III-D or III-F, they are included in Section III-E.

NOTE – For recombinant DNA experiments falling under Sections III-D-5-a through III-D-5-d, physical containment requirements may be reduced to the next lower level by appropriate biological containment practices, such as conducting experiments on a virus with an obligate insect vector in the absence of that vector or using a genetically attenuated strain.

Section III-D-5-a. BL3-P (Plants) or BL2-P + biological containment is recommended for experiments involving most exotic (see NIH Guidelines, Section V-M, *Footnotes and References of Sections I-IV*) infectious agents with recognized potential for serious detrimental impact on managed or natural ecosystems when recombinant DNA techniques are associated with whole plants.

Section III-D-5-b. BL3-P or BL2-P + biological containment is recommended for experiments involving plants containing cloned genomes of readily transmissible exotic (see NIH Guidelines, Section V-M, *Footnotes and References of Sections I-IV*) infectious agents with recognized potential for serious detrimental effects on managed or natural ecosystems in which there exists the possibility of reconstituting the complete and functional genome of the infectious agent by genomic complementation *in planta.* No BL3 laboratories exist in this facility.

Section III-D-5-c. BL4-P containment is recommended for experiments with a small number of readily transmissible exotic (see NIH Guidelines, Section V-M, *Footnotes and References of Sections I-IV*) infectious agents, such as the soybean rust fungus (*Phakospora pachyrhizi*) and maize streak or other viruses in the presence of their specific arthropod vectors, that have the potential of being serious pathogens of major U.S. crops. No BL4 laboratories exist in this facility.

Section III-D-5-d. BL3-P containment is recommended for experiments involving sequences encoding potent vertebrate toxins introduced into plants or associated organisms. Recombinant DNA containing genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD50 of <100 nanograms per kilogram body weight fall under Section III-B-1, *Experiments Involving the Cloning of Toxin Molecules with LD50 of Less than 100 Nanograms Per Kilogram Body Weight,* and require NIH/OBA and Institutional Biosafety Committee approval before initiation. No BL3 laboratories exist in

this facility.

Section III-D-5-e. BL3-P or BL2-P + biological containment is recommended for experiments with microbial pathogens of insects or small animals associated with plants if the recombinant DNA-modified organism has a recognized potential for serious detrimental impact on managed or natural ecosystems. No BL3 laboratories exist in this facility.

Section III-D-6. Experiments Involving More than 10 Liters of Culture
The appropriate containment will be decided by the Institutional Biosafety Committee. Where appropriate, Appendix K, *Physical Containment for Large Scale Uses of Organisms Containing Recombinant DNA Molecules*, shall be used. NIH Guidelines, Appendix K describes containment conditions Good Large Scale Practice through BL3-Large Scale. No BL3 laboratories exist in this facility.

Section III-E. Experiments that Require SRS&B Notice Simultaneous with Initiation.
Experiments not included in Sections III-A, III-B, III-C, III-D, III-F, and their subsections are considered in Section III-E. All such experiments may be conducted at BL1 containment. For experiments in this category, a registration document (see Section III-D, *Experiments that Require Institutional Biosafety Committee Approval Before Initiation*) shall be dated and signed by the investigator and filed with the SRS&B at the time the experiment is initiated. The SRS&B reviews and approves all such proposals, but SRS&B review and approval prior to initiation of the experiment is not required (see NIH Guidelines, Section IV-A, *Policy*). For example, experiments in which all components derived from non-pathogenic prokaryotes and non-pathogenic lower eukaryotes fall under Section III-E and may be conducted at BL1 containment.

Section III-E-1. Experiments Involving the Formation of Recombinant DNA Molecules Containing No More than Two-Thirds of the Genome of any Eukaryotic Virus. Recombinant DNA molecules containing no more than two-thirds of the genome of any eukaryotic virus (all viruses from a single Family being considered identical [see NIH Guidelines, Section V-J, *Footnotes and References of Sections I-IV]*) may be propagated and maintained in cells in tissue culture using BL1 containment. For such experiments, it must be demonstrated that the cells lack helper virus for the specific Families of defective viruses being used. If helper virus is present, procedures specified under Section III-D-3, *Experiments Involving the Use of Infectious Animal or Plant DNA or RNA Viruses or Defective Animal or Plant DNA or RNA Viruses in the Presence of Helper Virus in Tissue Culture Systems*, should be used. The DNA may contain fragments of the genome of viruses from more than one Family but each fragment shall be less than two-thirds of a genome.

Section III-E-2. Experiments Involving Whole Plants. This section covers experiments involving recombinant DNA-modified whole plants, and/or experiments involving recombinant DNA-modified organisms associated with whole plants, except those that fall under Section III-A, III-B, III-D, or III-F. It should be emphasized that knowledge of the organisms and judgment based on accepted scientific practices should be used in all cases in selecting the appropriate level of containment. For example, if the genetic modification has the objective of increasing pathogenicity or converting a non-pathogenic organism into a pathogen, then a higher level of containment may be

appropriate depending on the organism, its mode of dissemination, and its target organisms. By contrast, a lower level of containment may be appropriate for small animals associated with many types of recombinant DNA-modified plants.

Section III-E-2-a. BL1-P is recommended for all experiments with recombinant DNA-containing plants and plant-associated microorganisms not covered in Section III-E-2-b or other sections of the *NIH Guidelines*. Examples of such experiments are those involving recombinant DNA-modified plants that are not noxious weeds or that cannot interbreed with noxious weeds in the immediate geographic area, and experiments involving whole plants and recombinant DNA-modified non-exotic (see NIH Guidelines, Section V-M, *Footnotes and References of Sections I-IV*) microorganisms that have no recognized potential for rapid and widespread dissemination or for serious detrimental impact on managed or natural ecosystems (e.g., *Rhizobium* spp. And *Agrobacterium* spp.).

Section III-E-2-b. BL2-P or BL1-P + biological containment is recommended for the following experiments:

Section III-E-2-b- 1. Plants modified by recombinant DNA that are noxious weeds or can interbreed with noxious weeds in the immediate geographic area.

Section III-E-2-b- 2. Plants in which the introduced DNA represents the complete genome of a non-exotic infectious agent (see NIH Guidelines, Section V-M, *Footnotes and References of Sections I-IV*).

Section III-E-2-b- 3. Plants associated with recombinant DNA-modified non-exotic microorganisms that have a recognized potential for serious detrimental impact on managed or natural ecosystems (see NIH Guidelines, Section V-M, *Footnotes and References of Sections I-IV*).

Section III-E-2-b- 4. Plants associated with recombinant DNA-modified exotic microorganisms that have no recognized potential for serious detrimental impact on managed or natural ecosystems (see NIH Guidelines, Section V-M, *Footnotes and References of Sections I-IV*).

Section III-E-2-b- 5. Experiments with recombinant DNA-modified arthropods or small animals associated with plants, or with arthropods or small animals with recombinant DNA-modified microorganisms associated with them if the recombinant DNA-modified microorganisms have no recognized potential for serious detrimental impact on managed or natural ecosystems (see NIH Guidelines, Section V-M, *Footnotes and References of Sections I-IV*).

Section III-E-3. Experiments Involving Transgenic Rodents

This section covers experiments involving the generation of rodents in which the animal's genome has been altered by stable introduction of recombinant DNA, or DNA derived there from, into the germ-line (transgenic rodents). Only experiments that require BL1 containment are covered under this section; experiments that require BL2, BL3, or BL4 containment are covered under Section III-D-4, *Experiments Involving Whole Animals*. No BL3or BL4 laboratories exist in this facility.

Section III-F. Exempt Experiments.

The following recombinant DNA molecules are exempt from the *NIH Guidelines*:

Section III-F-1. Those that are not in organisms or viruses.

Section III-F-2. Those that consist entirely of DNA segments from a single nonchromosomal or viral DNA source, though one or more of the segments may be a synthetic equivalent.

Section III-F-3. Those that consist entirely of DNA from a prokaryotic host including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well established physiological means.

Section III-F-4. Those that consist entirely of DNA from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species).

Section III-F-5. Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. A list of such exchangers will be prepared and periodically revised by the NIH Director with advice of the RAC after appropriate notice and opportunity for public comment (see NIH Guidelines, Section IV-C-1-b- 1.-I, *Major Actions*). See NIH Guidelines, Appendices A-I through A-VI, *Exemptions Under Section III-F-5–Sublists of Natural Exchangers*, for a list of natural exchangers that are exempt from the *NIH Guidelines*.

Section III-F-6. Those that do not present a significant risk to health or the environment (see NIH Guidelines, Section IV-C-1-b- 1.-I, *Major Actions*), as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public comment. See NIH Guidelines, Appendix C, *Exemptions under Section III-F-6* for other classes of experiments, which are exempt from the *NIH Guidelines*.

APPENDIX B
EXAMPLES OF HIGHLY HAZARDOUS CHEMICALS (HHC)

- Chemicals regulated in an OSHA Substance-Specific Standard (e.g. methylene chloride or formaldehyde)
- Carcinogens (confirmed and suspected) as defined by any of the following organizations – International for Research on Cancer (IARC), the National Toxicology Program (NTP) or OSHA
- Chemicals that are described by their manufacturer as being "highly toxic", "poisonous", or "corrosive"
- Sensitizers
- Mutagens
- Reproductive toxins
- Teratogens
- Neurotoxins (*e.g.*, mercury)
- Chemicals that are described by their manufacturer as "highly" or "extremely flammable", "light sensitive", "peroxidizable", "pyrophoric", "unstable", "reactive" or "shock sensitive"
- Chemicals with an NFPA Fire or Reactivity Rating of 3 or greater
- Chemicals with an NFPA Special Hazard Rating of "Water Reactive"
- DOT Hazard Class of "Dangerous When Wet" (Class 4)
- DOT "Explosive" Hazard Class (Class 1)
- DOT "Flammable Gas" Hazard Class (Class 2)
- DOT "Flammable Liquid" Hazard Class (Class 3)
- DOT "Flammable Solid" Hazard Class (Class 4)
- DOT "Spontaneously Combustible" Hazard Class (Class 4)
- DOT "Organic Peroxide" Hazard Class (Class 5.2)

APPENDIX C
BIOSAFETY / BIOLOGICAL MATERIALS

A. General Information:

Microbes present in clinical or animal materials can produce an infection in a laboratory worker. Some of these infections can be life threatening, while others can be sub clinical and remain latent for long periods. Treatment may not be available for all pathogens transmissible to humans.

Every employee must assume that microbes with the potential to produce infectious disease are present in human and animal material handled in the laboratory, and must protect themselves, work associates, the public and family members from accidental infection.

Everyone must avoid accidental exposure or unprotected contact with these materials in the work place. This is accomplished with proper Biosafety training, practices, and through the proper use of protective equipment such as gloves, lab garments, eye, mouth and nose protection. When these precautions are properly used, safe work with biohazardous materials and pathogens can be achieved.

B. Biohazardous Substances:

1. It should be assumed that ALL human and primate blood, plasma, serum, body fluids (e.g., saliva, tears, cerebrospinal fluid, semen, and cervical secretions) unfixed tissues, and cell lines are contaminated with pathogenic agents that are transmissible to humans. Any human or primate material that contains even small amounts of blood is included in this category. Handle using BSL 2 precautions.
   In addition any human or animal material artificially exposed to infectious microbes is a biohazardous substance and should be handled with appropriate precautions.

2. Industry produced reagents derived from human and animal sources (e.g., serum, antibodies, reagents, and cell lines) must be handled in the appropriate setting with appropriate protective equipment.

3. Cultures of known agents are hazardous substances and should be handled with appropriate precautions. Refer to Table 1, **Appendix A** for appropriate classification.

4. Non-exempt recombinant microbes, especially those with pathogenic qualities may also be biohazardous.

C. Responsibilities of Staff:

1. Gain knowledge about the biohazardous material in the laboratory before initiating work. Ask the lab supervisor to explain any procedures or concepts that are not clear BEFORE beginning work

2. Understand the principles of good microbiological practice BEFORE working with biohazardous materials. This includes the use of aseptic technique, proper decontamination procedures, emergency biohazard spill management and the proper use of biosafety equipment.

D. Responsibilities of the Principal Investigator:

The Principal Investigator is responsible for carrying out the biosafety program in the laboratory. The laboratory director or designated supervisor should establish the biosafety level for each component of the work to be done and should ensure the facilities and equipment are adequate and in good working order, that initial and periodic training is provided to the staff, and that the recommended practices and procedures are strictly followed.

E. Laboratory Biosafety Practices:

1. All biohazardous work must be reviewed and approved by the R & D Committee and the SRS prior to its use.

2. The Principal Investigator or laboratory supervisor is responsible for:
    a. Assuring that all biohazardous work is registered and approved by the institution.
    b. Assuring that all biohazardous work is conducted in accordance with CDC or OSHA Biosafety Guidelines or regulations
    c. Assuring that all personnel strictly follow the recommended biosafety practices in the lab at ALL times and are informed of these practices.

3. The service chiefs are responsible for:
    a. Assuring that all PIs and laboratory supervisors in the department register their biohazardous work by following institutional procedures.
    b. Assuring that they are aware of all biohazardous work in their departments and that compliance is monitored.

4. All Laboratory personnel **MUST**:
    a. Wear appropriate personal protective clothing when handling biohazardous materials (gloves, lab coats / scrubs, glasses, shoe covers, sleeve protectors, etc.)
    b. NEVER mouth pipette. Use automatic pipettors equipped with filters when appropriate.
    c. Sterilize ALL biological materials, either by autoclaving or chemical treatment prior to disposal. Non-sterilized biohazardous materials are not to be placed into sewers.
    d. Become familiar with all laboratory and institutional biosafety materials describing the required precautions.
    e. Become familiar with the standard operating procedures for shipping and receipt of packages containing biological and biohazardous materials.
    f. Report all accidents, occurrences and unexplained illnesses to the work supervisor, infection control nurse or employee health physician. Understand the pathogenesis of the biohazards, which are being used or are present in the lab.

g. Protect fellow workers and the public from the pathogens used or present in laboratory materials.

F. Laboratory Biosafety Level Criteria:

Biosafety Level 1 (BSL1): Standard Microbiological Practices:

a. Access to the laboratory is restricted at the discretion of the laboratory director when experiments are in progress.
b. Refrigerators, incubators and any other places where biohazardous agents are used must be identified with a BIOHAZARD sticker.
c. Work surfaces are decontaminated daily and after any spill of viable material. 70% ETOH, 2% SDS (sodium dodecyl sulfate) or a microbicidal agent is recommended.
d. All contaminated liquid or solid wastes are decontaminated before disposal. Cell culture and supernates should be inactivated by mixing with a solution of 10% bleach before discarding.
e. Only mechanical pipetting devices are to be used. Tips should be ejected gently and directly into a biohazard receptacle.
f. Eating, drinking, smoking, and applying cosmetics is not permitted in the work area. Food storage is allowed only in designated (labeled) cabinets / refrigerators located outside the work area.
g. Hand washing is done immediately after handling any material and before leaving the laboratory. Only clean gloves should be worn outside the lab to transport materials and should not touch common surfaces.
h. All procedures will be performed carefully to minimize the formation of aerosols.
i. The wearing of laboratory coats, gowns, or uniforms is recommended to prevent contamination or soiling of street clothes.

Biosafety Level 2 (BSL2): includes all Level one procedures plus:

a. Contaminated waste that is to be decontaminated away from the lab is to be placed in a durable leak-proof container.
b. The lab director limits access to the lab.
c. Hazard warning signs that identify the infectious agent, list the names and telephone numbers of responsible personnel, and indicate the special requirements for entering the lab are to be placed on the access door to the lab.
d. Lab coats, gowns, smocks, etc. are to be worn inside the lab. All protective clothing used in the lab should be removed or covered by a clean gown before exiting the lab for non-laboratory areas.
e. Gloves must be worn to prevent skin contact with infectious material or when handling infectious animals.
f. All wastes from laboratories or animal rooms must be decontaminated before disposal.
g. The use of sharps (needles, scalpels) should be avoided whenever possible. Extreme caution should be used to prevent autoinoculation if sharps must be used. **Needles should not be bent, sheared, recapped or replaced following use.**

h. Spills and accidents that result in overt exposure to an infectious agent must be reported immediately to the lab director or to the Emergency room if during off-hours. Appropriate medical evaluation, surveillance, and treatment will be provided at no charge to the employee, and written records are maintained.
i. All personnel must read and understand the biosafety manual adopted by the lab, be advised of special hazards, and are expected to follow specified procedures and practices at all times.

Biosafety Level 3 (BSL3): Currently, there are no biosafety level 3 procedures conducted at this site, nor provisions for such.

G. Special Containment Equipment:

Recommended Precautions for Laboratory Work with Human Samples and Pathogens

TABLE 1
SUMMARY OF RECOMMENDED BIOSAFETY LEVELS FOR INFECTIOUS AGENTS

BSL	AGENTS	PRACTICES	PRIMARY BARRIERS AND SAFETY EQUIPMENT	FACILITIES (SECONDARY BARRIERS)
1	Not known to consistently cause diseases in healthy adults	Standard Microbiological Practices	None required	Open bench and sink required
2	• Agents associated with human disease • Routes of transmission include percutaneous injury, ingestion, mucous membrane exposure	BSL-1 practice plus: • Limited access • Biohazard warning signs • "Sharps" precautions • Biosafety manual defining any needed waste decontamination or medical surveillance policies	Primary barriers: • Class I or II BSCs or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials PPEs*: • Laboratory coats; gloves; face protection as needed	BSL-1 plus: • Autoclave available
3	• Indigenous or exotic agents with potential for aerosol transmission • Disease may have serious or lethal consequences	BSL-2 practice plus: • Controlled access • Decontamination of all waste • Decontamination of laboratory clothing before laundering • Baseline serum	Primary barriers: • Class I or II BSCs or other physical containment devices used for all open manipulation of agents PPEs*: • Protective laboratory clothing; gloves; respiratory protection as needed	BSL-2 plus: • Physical separation from access corridors • Self-closing, double-door access • Exhaust air not recirculated • Negative airflow into laboratory
4	• Dangerous/exotic agents which pose high risk of life-threatening disease • Aerosol-transmitted laboratory infections have occurred; or related agents with unknown risk of transmission	BSL-3 practices plus: • Clothing change before entering • Shower on exit • All material decontaminated on exit from facility	Primary barriers: • All procedures conducted in Class III BSCs or Class I or II BSCs in combination with full-body, air-supplied, positive pressure personnel suit	BSL-3 plus: • Separate building or isolated zone • Dedicated supply and exhaust, vacuum, and decontamination systems • Other requirements outlined in the text

* PPE – Personal Protective Equipment

Table taken from *Biosafety in Microbiological and Biomedical Laboratories*; 5th Edn (2007)

H. Spill Procedure for Biological Agents- listed in order of priority.

1. Protection of Personnel

a. Notify all personnel in the immediate area. Evacuate the area and keep personnel clear for at least 30 minutes.
b. Remove any contaminated clothing and leave contaminated area. All exposed portions of the body should be washed with soap and water for 15 minutes. If eyes are involved they are to be flushed for 15 minutes. Medical advice should be sought for possible prophylaxis.
c. Post notices on entrance alerting people not to enter the contaminated area; Specify type of accident, organism involved, date and time of accident.
d. Notify the Principal Investigator, Research Office and the Safety Office and/or Hazardous Materials Manager.

2. Protection of Research Lab and Building Facility

a. Allow 30 minutes for aerosols to settle before beginning decontamination.
b. Wear personal protective gear including gloves, mask, shoe protection, and lab coat.
c. Place absorbent towels over spilled substance and flood towel from the outside inward with a 10% solution of freshly diluted bleach. Leave towel down for at least 10 minutes. Wash down all surfaces in lab. Place all waste in biohazard bag, autoclave, date and label with autoclave tape "Rendered Harmless" before disposal.

APPENDIX D
CHEMICAL COMPATIBILITY CHART

Below is a chart adapted from the CRC Laboratory Handbook which groups various chemicals in to 23 groups with examples and incompatible chemical groups. This chart is by no means complete but it will aid in making decisions about storage. For more complete information please refer to the MSDS or SDS for the specific chemical. The MAXCOM database provides chemical compatibility guidance for all chemicals listed in each laboratory.

Group	Name	Example	Incompatible Groups
Group 1	Inorganic Acids	Hydrochloric acid Hydrofluoric acid Hydrogen chloride Hydrogen fluoride Nitric acid Perchloric acid Sulfuric acid Phosphoric acid	2,3,4,5,6,7,8,10,13,14,16,17,18,19,21,22,23
Group 2	Organic acids	Acetic acid Butyric acid Formic acid Propionic acid	1,3,4,7,14,16,17,18,19,22
Group 3	Caustics	Sodium hydroxide Ammonium hydroxide solution	1,2,6,7,8,13,14,15,16,17,18,20,23
Group 4	Amines and Alkanolamines	Aminoethylethanolamine Aniline Diethanolamine Diethylamine Dimethylamine Ethylenediamine 2-Methyl-5-ethylpyridine Monoethanolamine Pyridine Triethanolamine Triethylamine Triethylenetetramine	1,2,5,7,8,13,14,15,16,17,18,23
Group 5	Halogenated Compounds	Allyl chloride Carbon tetrachloride Chlorobenzene Chloroform Methylene chloride Monochlorodifluoromethane 1,2,4-Trichlorobenzene 1,1,1-Trichloroethane	1,3,4,11,14,17

		Trichloroethylene Trichlorofluoromethane	
Group 6	Alcohols Glycols Glycol Ether	1,4-Butanediol Butanol (iso, n, sec, tert) Diethylene glycol Ethyl alcohol Ethyl butanol Ethylene glycol Furfuryl alcohol Isoamyl alcohol Methyl alcohol Methylamyl alcohol Propylene glycol	1,7,14,16,20,23
Group 7	Aldehydes Acetaldehyde	Acrolein Butyraldehyde Crotonaldehyde Formaldehyde Furfural Paraformaldehyde Propionaldehyde	1,2,3,4,6,8,15,16,17,19,20,23
Group 8	Ketones	Acetone Acetophenone Diisobutyl ketone Methyl ethyl ketone	1,3,4,7,19,20
Group 9	Saturated Hydrocarbons	Butane Cyclohexane Ethane Heptane Paraffins Paraffin wax Pentane Petroleum ether	20
Group 10	Aromatic Hydrocarbons	Benzene Cumene Ethyl benzene Naphtha Naphthalene Toluene Xylene	1,20
Group 11	Olefins	Butylene 1-Decene 1-Dodecene Ethylene Turpentine	1,5,20
Group 12	Petroleum Oils	Gasoline Mineral Oil	20
Group 13	Esters	Amyl acetate Butyl acetates	1,3,4,19,20

		Castor oil Dimethyl sulfate Ethyl acetate	
Group 14	Monomers Polymerizable Esters	Acrylic acid Acrylonitrile Butadiene Acrylates	1,2,3,4,5,6,15,16,19,20,21,23
Group 15	Phenols	Carbolic acid Cresote Cresols Phenol	3,4,7,14,16,19,20
Group 16	Alkylene Oxides	Ethylene oxide Propylene oxide	1,2,3,4,6,7,14,15,17,18,19,23
Group 17	Cyanohydrins	Acetone cyanohydrin Ethylene cyanohydrin	1,2,3,4,5,7,16,19,23
Group 18	Nitriles	Acetonitrile Adiponitrile	1,2,3,4,16,23
Group 19	Ammonia	Ammonium Hydroxide Ammonium Gas	1,2,7,8,13,14,15,16,17,20,23
Group 20	Halogens	Chlorine Fluorine	3,6,7,8,9,10,11,12,13,14,15,19,21,22
Group 21	Ethers	Diethyl Ether THF	1,14,20
Group 22	Phosphorus	Phosphorus, Elemental	1,2,3,20
Group 23	Acid Anhydrides	Acetic anhydride Propionic anhydride	1,3,4,6,7,14,16,17,18,19

APPENDIX E
FLAMMABLE CHEMICAL GUIDELINES

A. DEFINITIONS:

1. Flammable chemicals refer to those having a boiling point at or below 100 degrees Fahrenheit, and a flash point below 73 degrees F.

2. "Large volume" refers to a volume of more than 125 milliliters (e.g.: performing an extraction with 250cc of ether at once).

B. POLICY:

1. Laboratories following these procedures shall not be obliged to obtain any separate approval for any use (including anesthesia) of volatile flammable reagents. Exceptions:
   a. The use of ethyl ether in the Veterinary Medical Unit for animal anesthesia is generally not permitted. An exemption may be granted by filing a Request to Use Explosive Anesthetic Agent(s) with the Subcommittee on Research Safety as well as obtaining a letter of approval from the Chair of the R&D Committee.
   b. The use of large volumes of flammable chemicals at any one time for a single experiment must be approved by the SRS.

C. GENERAL PROCEDURES

1. Container size shall be limited to 1 gallon if glass, and 5 gallons if the container is an approved metal or plastic safety can.

2. Ethyl ether for anesthesia shall be obtained in ¼-pound safety cans or 100 ml bottles. All ether shall be stored in designated flammable storage (explosion-proof) refrigerators or freezers and only used in explosion proof fume hoods.

3. Cans of ether, once opened, should be dated and stored in a flammable storage cabinet or explosion proof refrigerator. Unused quantities should be disposed of no later than 1 year from the date of opening.

4. Storing open containers of flammable /volatile reagents is prohibited.

5. Be familiar with the station fire prevention policies. Know the escape routes from the laboratory. All labs planning to use volatile flammable reagents must be equipped with appropriate dry chemical fire extinguishers and lab personnel must be trained in the proper use of this equipment.

APPENDIX F
CHEMICAL RESISTANCE SELECTION CHART FOR PROTECTIVE GLOVES

VG = Very Good, G = Good, F = Fair, P = Poor (Not Recommended)

Chemical	Neoprene	Latex/Rubber	Butyl	Nitrile
Acetaldehyde*	VG	G	VG	G
Acetic acid	VG	VG	VG	VG
Acetone*	G	VG	VG	P
Ammonium hydroxide	VG	VG	VG	VG
Amy acetate*	F	P	F	P
Aniline	G	F	F	P
Benzaldehyde*	F	F	G	G
Benzene*	P	P	P	F
Butyl acetate	G	F	F	P
Butyl alcohol	VG	VG	VG	VG
Carbon disulfide	F	F	F	F
Carbon tetrachloride*	F	P	P	G
Castor oil	F	P	F	VG
Chlorobenzene*	F	P	F	P
Chloroform*	G	P	P	F
Chloronaphthalene	F	P	F	F
Chromic acid (50%)	F	P	F	F
Citric acid (10%)	VG	VG	VG	VG
Cyclohexanol	G	F	G	VG
Dibutyl phthalate*	G	P	G	G
Diesel fuel	G	P	P	VG
Diisobutyl ketone	P	F	G	P
Dimethylformamide	F	F	G	G
Dioctyl phthalate	G	P	F	VG
Dioxane	VG	G	G	G
Epoxy resins, dry	VG	VG	VG	VG
Ethyl acetate*	G	F	G	F
Ethyl alcohol	VG	VG	VG	VG
Ethyl ether*	VG	G	VG	G
Ethylene dichloride*	F	P	F	P
Ethylene glycol	VG	VG	VG	VG
Formaldehyde	VG	VG	VG	VG

Formic acid	VG	VG	VG	VG
Freon 11	G	P	F	G
Freon 12	G	P	F	G
Freon 21	G	P	F	G
Freon 22	G	P	F	G
Furfural*	G	G	G	G
Gasoline, leaded	G	P	F	VG
Gasoline, unleaded	G	P	F	VG
Glycerin	VG	VG	VG	VG
Hexane	F	P	P	G
Hydrazine (65%)	F	G	G	G
Hydrochloric acid	VG	G	G	G
Hydrofluoric acid (48%)	VG	G	G	G
Hydrogen peroxide (30%)	G	G	G	G
Hydroquinone	G	G	G	F
Isooctane	F	P	P	VG
Kerosene	VG	F	F	VG
Ketones	G	VG	VG	P
Lacquer thinners	G	F	F	P
Lactic acid (85%)	VG	VG	VG	VG
Lauric acid (36%)	VG	F	VG	VG
Lineolic acid	VG	P	F	G
Linseed oil	VG	P	F	VG
Maleic acid	VG	VG	VG	VG
Methyl alcohol	VG	VG	VG	VG
Methylamine	F	F	G	G
Methyl bromide	G	F	G	F
Methyl chloride*	P	P	P	P
Methyl ethyl ketone*	G	G	VG	P
Methyl isobutyl ketone*	F	F	VG	P
Methyl metharcrylate	G	G	VG	F
Monoethanolamine	VG	G	VG	VG
Morpholine	VG	VG	VG	G
Naphthalene	G	F	F	G
Napthas, aliphatic	VG	F	F	VG
Napthas, aromatic	G	P	P	G
Nitric acid*	G	F	F	F
Nitric acid, red and white	P	P	P	P

fuming				
Nitromethane (95.5%)*	F	P	F	F
Nitropropane (95.5%)	F	P	F	F
Octyl alcohol	VG	VG	VG	VG
Oleic acid	VG	F	G	VG
Oxalic acid	VG	VG	VG	VG
Palmitic acid	VG	VG	VG	VG
Perchloric acid (60%)	VG	F	G	G
Perchloroethylene	F	P	P	G
Petroleum distillates (naphtha)	G	P	P	VG
Phenol	VG	F	G	F
Phosphoric acid	VG	G	VG	VG
Potassium hydroxide	VG	VG	VG	VG
Propyl acetate	G	F	G	F
Propyl alcohol	VG	VG	VG	VG
Propyl alcohol (iso)	VG	VG	VG	VG
Sodium hydroxide	VG	VG	VG	VG
Styrene	P	P	P	F
Styrene (100%)	P	P	P	F
Sulfuric acid	G	G	G	G
Tannic acid (65)	VG	VG	VG	VG
Tetrahydrofuran	P	F	F	F
Toluene*	F	P	P	F
Toluene diisocyanate (TDI)	F	G	G	F
Trichloroethylene*	F	F	P	G
Triethanolamine (85%)	VG	G	G	VG
Tung oil	VG	P	F	VG
Turpentine	G	F	F	VG
Xylene*	P	P	P	F

Note: When selecting chemical-resistant gloves be sure to consult the manufacturer's recommendations, especially if the gloved hand(s) will be immersed in the chemical.

APPENDIX G

LABORATORY START-UP AND CLOSEOUT
VA Western New York Healthcare System
Research and Development

Introduction

This section has been included to provide guidance to all principal investigators (PIs) on appropriate "start-up" and "close-out" procedures. It is imperative that these procedures be followed to ensure compliance with all applicable federal, state and local requirements

Laboratory Start-Up

It is necessary that each new Principal Investigator (PI) be made aware of all applicable safety requirements. Failure to incorporate required work practices may lead to an unsafe occupational setting. Such non-compliance may also result in fines from external regulatory agencies such as the Occupational Safety and Health Administration (OSHA) or the Nuclear Regulatory Commission (NRC).

New PIs are to complete the "Notice of Laboratory Occupancy" form (**Appendix H**). The PI can request assistance in completing the form and answering questions regarding special safety requirements applicable to her/his laboratory operation by contacting the Research Laboratory Safety Coordinator.

Laboratory Relocation or Closeout

When changes in laboratory occupancy occur, it is important to address any potential issues before the occupant(s) leaves.

It is imperative that all laboratory closeouts be conducted while conforming to standard procedures for the removal of hazardous materials. The Research Laboratory Safety Coordinator shall be notified at least 30 days prior to anticipated departure. Notice is given by completing the Laboratory Closeout Notice (**Appendix I**) and forwarding it to the Research Office, Fax # 862-6526. If a laboratory is authorized to use radioactive materials, forward a copy of this form to the Radiation Safety Officer (Routing Symbol #115) and call the Health Physics Office at extension 5226. Upon receipt, the PI will be provided specific instructions for proper shut-down. The departing PI shall be held fully responsible for all facility requirements. The laboratory will be cleared for new occupancy only after all requirements are met.

Should proper notification not be given or facility requirements not met, the PI and/or the PI's department will be held responsible for all costs incurred for safe disposal of remaining hazardous material wastes and attendant lab clean-up.

The following is a list of requirements which must be met for each class of hazardous agents used before a laboratory is released.

Biological Hazards

1. All biological materials (*i.e.*, blood, fresh tissue, bacterial cultures, etc.,) must be removed from the laboratory by disposing according to Institutional policy, by shipping to another facility while conforming to approved shipping regulations, or by transferring to another PI. This includes those materials stored in refrigerators, freezers, incubators and coldrooms.

2. All equipment which has come in contact with potentially infectious materials must be properly decontaminated.

3. All biological waste must be properly decontaminated and disposed of appropriately.

4. All benchtops or other work surfaces on which biological materials were manipulated must be wiped down with an approved disinfectant.

5. All biological safety cabinets will be decontaminated. If a formaldehyde gas decontamination is deemed necessary, the departing PI will be financially responsible.

Chemical Hazards

1. All chemical containers are labeled with the chemical name or a best description of the compound.

2. Properly completed waste request forms are completed for all chemicals not transferred to another laboratory.

3. Chemicals being shipped or transferred to another facility, must be packaged and labeled according to approved regulations.

4. Compressed gas cylinders are to be returned to their supplier (e.g., Praxair).

Radioactive Material Hazards

1. Follow the directions noted above under, "Laboratory Relocation or Closeout". Notify the Radiation Safety Officer (RSO) at extension 5226 of intention to terminate authorization.

2. Disposal or transfer of radioactive materials must be coordinated with the RSO.

3. Perform a thorough direct and removable radioactive material contamination survey of the laboratory, including equipment, radioactive sinks, floors, countertops, etc. to determine if contamination present exceeds any applicable action level. Those areas found to exceed the applicable action levels must be decontaminated and resurveyed until within allowable limits.

APPENDIX H

NOTICE OF LABORATORY OCCUPANCY

VA Western New York Healthcare System
Research and Development

In order to assure total compliance with all applicable safety policies and procedures, it is necessary for new principal investigators to communicate with the designated Research Laboratory Safety Officer and the Industrial Hygiene and Safety Manager. Upon receipt of the following list, an on-site visit to discuss all applicable safety policies and procedures will be scheduled.

P.I.: _____ **Dept: _____**

Building: _____ **Room(s): _____**

Phone: _____ **E-mail: _____**

Start Date of Lab Work: _____

In the space provided, give a general description of all hazardous agents to be used in the new laboratory (including all materials that are anticipated to be used in the future). If you are uncertain whether an agent should be considered "hazardous", list it below so it can be discussed during the Industrial Hygienist on-site visit.

Biological Materials (*i.e.*, viruses, bacteria, human blood, etc.):

_____
_____
_____

Chemicals (list all Particularly Hazardous Substances) :

_____
_____
_____
_____

Radioactive Materials:
1.Were you authorized to use RAM at your last place of employment or work in a laboratory where you were authorized to handle RAM? YES G NO G
(<u>If YES</u>, indicate the nuclides used and provide contact information for the Radiation Safety Officer at that facility.)

2. Was any equipment used in the storage or use of RAM? YES G NO G
(If YES, identify that equipment and provide documentation that all equipment is free of contamination and stored RAM.)

3.If you were authorized to use RAM at any facility prior to your last palce of employment, confirm that no RAM or contamination from RAM is present in or on any equipment you plan to bring into this facility.

Animals (List all to be used):

Fax completed form to the Research Laboratory Safety Officer (FAX# 862-6526). Queries regarding this form should be directed to the Research Office (ext 6528) or the Safety Office (ext 8826).

APPENDIX I

LABORATORY CLOSEOUT NOTICE

VA Western New York Healthcare System
Research and Development

Complete this closeout notice as soon as a move is indicated (preferably 3-4 months) and **no less than 30 days prior to departure**. Send the completed form to the Research Laboratory Safety Officer **(**Fax # 862-6526). Once the notice is received, the laboratory will be contacted with instructions for proper closeout.

P.I.: _____ **Department: _____**

Building: _____ **Room(s): _____**

Lab Contact: _____ **Phone: _____**

Box #: _____
Safety Contact:_____ **Email: _____**

***Please check one of the following*:**

☐ **Permanent Lab Closeout** ☐ **Laboratory Relocation**

Anticipated Date of Departure: _____

Hazardous Material Inventory

List the laboratory's hazardous materials while segregating by the categories below. A brief description of each material (i.e. quantity) will be helpful when preparing site-specific instructions for closeout.

Biological Materials:

_____
_____
_____

Radioactive Materials:

_____
_____

Chemicals (List all particularly hazardous chemicals – Categorize others by hazard class):

_____
_____
_____
_____
_____

APPENDIX J

CHECKLIST FOR VACATING LABORATORIES
VA Western New York Healthcare System

Laboratory Information

Laboratory to be vacated:
Building_____Room(s):_____

Principal Investigator:_____
Department:_____

Date laboratory will be vacated:_____

When vacating a laboratory, the PI must either move, discard or transfer responsibility for all potentially hazardous materials.

CHECKLIST

Check N/A

Chemicals/Gas Cylinders

If transferring usable chemicals/gases to another lab, contact Safety Office for procedure
o o
Return gas cylinders to SPD or supplier
o o
Label, with hazardous waste tags, all gas cylinders that cannot be returned to supplier
o o
Insure all waste chemicals are in sealed, compatible containers
o o
Contact Safety Office for information concerning packaging chemically-contaminated materials
o o
Identify all waste chemicals with full chemical name(s) using hazardous waste tags
o o
Submit Hazardous Waste Removal Request Form via the Internet
o o
Contact Safety Office if unknown chemicals/gases are present
o o
Confirm that all chemical/gases have been removed from lab and support spaces
o o
Clean all laboratory surfaces including hoods and storage cabinets
o o

Controlled Substances

Contact Safety for disposal and permit transfer/deactivation instructions
o o

Microorganisms, Cultures, Recombinant Organisms

Autoclave all cultures and solid, non-sharp biological waste in **red bags** and **date and label** with autoclave tape “Rendered harmless”
o o
If autoclave not available, place in incinerator box and request pickup from Safety Office
o o
Add bleach to liquid waste to final concentration of 10%, then pour down drain
o o
Place needles and syringes in sharps containers and request pickup from Safety Office
o o
Disinfect benches and equipment used with cultures
o o
Contact Safety Office to schedule decontamination of biological safety cabinets
o o

If cultures are shipped to another facility, all shipping regulations must be followed

o o

Cultures to be moved within campus must be transported in a primary and secondary container

o o

Animal and Human Tissue

Autoclave all animal carcasses/tissue and dispose in VMU walk in refrigerator

o o

Label with autoclave tape “Rendered harmless”

Autoclave all human tissue in plastic bag and dispose

o o

Label with autoclave tape “Rendered harmless”

Separate preserved tissue from liquid, place tissue in incinerator box

o o

Dispose of liquid preservative as chemical waste

o o

Radioactive Materials

Package all materials in approved and labeled waste containers

o o

Complete radioactive waste inventory forms and attach to containers

o o

Request removal of radioactive waste by contacting Health Physics Office

o o

Perform contamination survey, decontaminate and re-survey if necessary

o o

Schedule closeout survey and safety inspection with the Health Physics Office

o o

Arrange for a responsible person to be present during survey

o o

Remove all radiation signs, stickers, postings, etc. after instructed to do so by Health Physics Staff

o o

Return all Inventory/Disposal Records to the Health Physics Office

o o

Equipment and Lab Furniture

Clean or decontaminate equipment or furniture to be left in lab, including fume hoods

o o

Label non-working equipment with operational deficiency

o o

Contact Safety Office for information regarding contaminated equipment

o o

Shared Storage Areas

Check all shared areas for hazardous materials

o o

Mixed Hazards

If mixed hazards are identified, contact Safety Office for guidance

o o

Lab Inspection

Request exit inspection by Safety Office

o o

Research Clearance

a. Principal Investigator’s Agreement:

I certify that my staff and I have adequately cleaned and decontaminated the laboratories under my supervision and all supplies, chemicals and non-VA equipment have been removed. VA Research Service equipment and furniture will remain in the lab.

_____ _____
Principal Investigator Signature Date

b. ACOS for Research & Development

The laboratory has been cleared of all materials with the exception of furniture and permanent equipment to remain in the lab. I am aware of the status of the lab(s) being vacated

_____ _____
ACOS/R&D Signature Date

Health Physics Office Clearance

____Lab has been cleared of all radioactive substances and have been properly disposed.

_____ _____
Signature Date

Safety Office Clearance

After Research Service and Radiation Safety Office has signed the form, return the signed copy to Safety Office for final clearance – Safety Office (Basement, A-wing)

____Lab has been cleared of biological material

_____ _____

____Lab has been cleared of chemicals

_____ _____

____Lab has been cleared of radioactivity

_____ _____
Signature Date

If you have questions, contact the Research Office (ext 6528)

APPENDIX K.
GENERAL SAFETY PROCEDURES
FOR THE VETERINARY MEDICAL UNIT (VMU)

A. Uniform and Personnel Hygiene

1. Uniforms will be provided for all Veterinary Medical Unit (**VMU**) personnel.

2. Employees are to put on uniforms immediately after arrival each morning and remove them before departure each evening. Uniforms are not to be worn away from the VA.

3. Investigators working with animals in the VMU will be provided with protective clothing (*i.e.*, scrubs for surgery) sterile and non-sterile gloves, and special handling gloves as needed.

4. All personnel who come in contact with animals or animal tissues should wash carefully with soap and water immediately after procedures are finished.

B. Safety Rules

1. The use of ether as an anesthetic for animals is **prohibited**. Information concerning exceptions to this policy can be found in VA Department of Medicine and Surgery Manual (M-3, Part I, Section 12.04 (j) (*Use of explosive Anesthetic Agents in Animal Facilities*).

2. New investigators or technicians wishing to use animals must first complete a Training Checklist and a Preventative Medicine Program Form prior to receiving authorization to utilize animals. In addition, anyone utilizing animals is required to attend the Animal Handling Training Course conducted by the consulting veterinarian or SUNYAB Laboratory Animal Facilities. In the interim, any animal handling questions should be directed to the Supervisor of the VMU, who can provide instructions on proper animal handling techniques, or for assistance in working with unfamiliar species.

3. Eyewash stations are located in the Common Lab (B137), in the Necropsy Room (B114), and in the dirty area of cage washing (B109).

4. Eating, drinking, and smoking are not permitted in the animal rooms or animal research laboratories.

C. Fire and Emergency Evacuation

1. All personnel should be aware that if there is a power failure, there are emergency lights that will go on in the VMU.

2. In the event there is a fire or some other incident that requires an evacuation, all personnel should follow the exit signs that point to the two stairwells, and then exit through the emergency doors which are located on the landings where the gates are located.

D. Preventative Medicine Program (PMP)

All personnel (both VA and WOC) with exposure to animals or access to the VMU are required to complete the PMP form annually. Forms are to be turned into Employee Health to be risked assessed by the Employee Health Physician.

1. The following will be provided for all VMU employees:

a. A physical examination will be given at the time of employment and annually thereafter.

b. A PPD test will be given annually. Personnel with a history of exposure to tuberculosis or who have received the BCG vaccine will automatically be given special consideration.

c. A blood sample will be taken annually from all VMU personnel. (SMA 12 and CBC)

2. The following optional procedures will be offered to all personnel on a voluntary basis:

a. Tetanus immunization

b. VA employees with significant contact with dogs, cats, bats or wild carnivores will be provided the opportunity of receiving pre-exposure immunization with **HDCV** (human diploid cell rabies vaccine). The potential dangers of the rabies vaccine should be made known to the employee.

c. M.D. and Ph.D. investigators who have frequent contact with animals are covered by the physical examination procedures outlined in Medical Center Memorandum llC-7, "*Voluntary Physical Exams or Screening*".

d. Both Investigators and VMU personnel working with animal subjects with possible zoonoses (a pathogen that can be transferred from animal subject to humans and back again, *i.e.*, Herpes B virus, rat-bite fever, infectious diseases) will be given instructions and guidelines for preventative measures.

e. Principal Investigators working with infectious diseases will provide VMU personnel precise guidelines for dealing with the specific pathogens involved.

E. Disposal of Animal Carcasses

1. **Under no circumstances will any dead animal or animal tissues be included in the trash that is handled by the hospital housekeeping personnel.**

2. All animal carcasses should be refrigerated (with the approval of PI) immediately after death, or frozen for long-term storage. If carcasses do not need to be frozen, they should be placed in opaque, waterproof bags, before being placed in the Necropsy Room (B114) refrigerator. Bags may be obtained from VMU personnel. Animal carcasses are transported from the refrigerator to the Waste Management area every 10 to 14 days, for packing and shipping. Carcasses are to be doubled bagged and then boxed. Boxes should be packed to weigh no more than 35 lbs.

3. Excess animals which have not had any experimentation done on them or are the wrong genotype may be euthanized using CO_2 and frozen for use in the SPCA Wildlife Rehabilitation Program. See VMU Supervisor for details.

4. Disposal of radioactive animal carcasses is listed in **APPENDIX L**. "Standard Operating Procedures for Radioactive Material (RAM) Safety in the Veterinary Medical Unit (VMU)."

APPENDIX L.
STANDARD OPERATING PROCEDURES FOR RADIOACTIVE MATERIALS SAFETY IN THE VETERINARY MEDICAL UNIT (VMU)

1. These instructions apply to animals involved in research with radioactive materials (**RAM**) or specific radiation sources. This process will be coordinated with Health Physics and are the ultimate responsibility of the principal investigator. Animals irradiated with external beams of x-ray or gamma rays are not made radioactive and do not constitute a radiological hazard. See VMU SOP for specific instructions on treating privately owned hyperthyroid cats.

2. All studies employing the use of RAM in laboratory animals shall have been approved in advance by the Radiation Safety Committee (**RSC**). Each investigator is expected to understand and comply fully with the rules and regulations of the Nuclear Regulatory Commission (**NRC**) pertaining to safe handling of RAM. Negligence in complying with safety measures and in the maintenance and reporting of accurate records of use and disposal of RAM will result in cancellation of privileges.

3. Persons engaged in use of radioisotopes shall familiarize themselves with the VHAUNYHS-Buffalo "*Radiation Protection Program Manual Vo1.1*". Questions concerning the use of radioisotopes should be directed to the Radiation Safety Officer (**RSO**) at extension 5226 or 5225.

4. Before new protocols employing RAM are allowed to begin, the Supervisor, Veterinary Medical Unit is to be informed of the animal species and isotope being used, as well as the appropriate research committee.

5. Radiation exposure monitoring devices are required when an individual works with certain RAM. The RSC will determine which individuals will be required to wear monitoring devices.

6. Areas designated for animal studies using RAM are restricted areas and are therefore accessible only to authorized personnel.

7. Following the use of radioactive materials in the VMU, research technicians or investigators will perform a fixed and removable survey of the work area as outlined in the manual referenced in #3, above. If the radiological survey determines contaminants in excess of those action levels listed in the *Radiation Protection Program Manua*l, decontamination and re-surveying should be performed until the levels are determined to be below those action levels. Results of all surveys should be sent to the Medical Center Health Physicist in Room 429C (115). Please contact the Assistant Health Physicist or RSO if there are any questions or problems.

8. When animals are to be returned to cages following administration of radioactive material, the Supervisor, Veterinary Medical Unit will be so informed. Such animals shall be placed in metabolism cages or other caging systems that permit collection of urine, feces, and bedding. Protective gloves, laboratory coats and other RSC required safety equipment will be worn while cleaning or otherwise

handling cages or waste trays in which animals containing radioactivity are housed. Cages housing animals containing radioactivity shall be labeled with a radioactive material sign, the investigator name, isotope, amount of activity, and the date of administration. The room in which these animals are housed shall be locked when authorized personnel are not present.

9. Following the death of an animal that contains radioactive material, the carcass shall be placed in a polyethylene bag, and the bag shall be labeled with a radioactive material sign, isotope, amount of activity, and disposal date. Carcasses should be stored in an approved RAM waste freezer and appropriate documentation should be attached to the side of the freezer. All freezers used for the storage of animals containing RAM shall be locked when RSC approved personnel are not present. All radioactive waste storage and disposal details will be outlined in your original RSC application concerning the study in question.

10. When a study is terminated and the animal subject is removed from a cage, the cage shall be manually cleaned and then monitored for fixed and removable contaminants. This process will be coordinated with Health Physics and is the ultimate responsibility of the principal investigator. The results of this survey shall be documented on the Laboratory Survey Form.

11. In case of a radiation spill or an accident, follow the spill guidelines outlined in the Radiation Protection Program Manual.

12. Authorized Principal Investigators have the ultimate responsibility for the acquisition, record keeping, disposal and decontamination of all radioactive material used in the course of their experiments. All RAM received at this facility shall be delivered to the Nuclear Medicine Department for monitoring. Veterinary Medical Unit personnel responsibility is limited only to the care of animals receiving radioactive material. All such care shall be previously approved by the RSC. All other aspects are the responsibility of the individual investigator.

APPENDIX M.
SAFETY IN THE INFECTIOUS DISEASE SUITE OF THE VMU

1. Veterinary Medical Unit personnel will wear prescribed protective clothing when working in the infectious disease suite when the area is being used for infectious disease studies. Prescribed protective clothing shall consist of a surgical gown, disposable gloves, shoe covers and a mask. This clothing is to be put on upon entering the room and removed on departure. Clothing worn in this area is not to be worn in any other area.

2. Feeding, watering and cleaning schedules are as for each species in conventional housing (see standard operating procedures for each species).

3. All bedding, cages and clothing shall be decontaminated by processing through the pass-through autoclave before leaving the infectious disease area.

4. Individual rooms will be thoroughly scrubbed with an approved disinfectant whenever it is empty or before introducing new animals.

5. Each room is to be clearly marked with name of hazardous agent, the responsible investigator and any special instructions.

6. Inventories are to be kept current following instruction for individual species.

7. Arrangements are to be cleared with the VMU Supervisor before introducing any new animals into the infectious disease ward.

REFERENCES:

a. Occupational Exposure to Hazardous Chemicals in Laboratories, OSHA 29 CFR 1910.1450

b. National Institutes of Health, NIH Guidelines for the Laboratory use of Chemical Carcinogens, NIH Pub. No. 81-2385, GPO, Washington, DC

c. OSHA Hazardous Waste and Emergency Response Standard, 29 CFR 1910.120

d. National Fire Protection Association, Fire Protection for Laboratories Using Chemicals NFPA-45

e. American Conference of Governmental Industrial Hygienists, Threshold Limit Values for Chemical Substances and Physical Agents in the Workroom Environment with Intended Changes, 6500 Glenway Avenue, Bldg. D-7, Cincinatti, OH 45211-4438

f. Code of Federal Regulations, 29 CFR part 1910 subpart Z. U.S. Govt. Printing Office, Washington, DC 20402